85-478

No.

Supreme Court, U.S.
FILED
SEP 20 1985
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

QUESTIONS PRESENTED

1) Whether this Court should resolve a conflict between the Third Circuit and this Court as to the rule of law governing the functionality of trade dress for prescription drugs?

2) Whether the Third Circuit may continue to impose upon generic drug manufacturers a standard of contributory liability for unfair competition based upon "reasonable anticipation", where this Court held in *Inwood v. Ives* that such a standard is "watered down and incorrect"?

3) Whether a trade dress feature is non-functional as a matter of law solely because other companies can enter the market without copying, when copying provides legitimate benefits to patients and health care professionals?

4) Whether a federal court may apply state law against unfair competition to prohibit the act of copying and selling functional product features?

STATEMENT PURSUANT TO SUPREME COURT RULES 21 AND 28.1

There were no other parties to the proceeding in the court whose judgment is sought to be reviewed.

Par Pharmaceutical, Inc. has no parent, subsidiary or affiliated corporation.

TABLE OF CONTENTS

	Page
Questions Presented	i
Statement Pursuant to Supreme Court Rules 21 and 28.1	ii
Table of Contents	iii
Table of Authorities	iv
Opinions Below	1
Jurisdiction	2
Constitutional Provisions and Statutes Involved	2
Statement of the Case	2
Reasons for Granting the Writ	9
I. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE CONFLICT BETWEEN THE STANDARD OF FUNCTIONALITY IN *INWOOD v. IVES* AND THE NEW RULE OF FUNCTIONALITY IN THE THIRD CIRCUIT	9
II. CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE STANDARD OF CONTRIBUTORY LIABILITY BASED UPON "REASONABLE ANTICIPATION" CAN SURVIVE AFTER *INWOOD v. IVES*	13
Conclusion	18

TABLE OF AUTHORITIES

Cases Cited:	Page
CIBA-Geigy Corp. v. Bolar Pharmaceuticcal Co., Inc., 547 F.Supp. 1095 (D.N.J. 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983), *cert. denied*, ____ U.S. ____, 1094 S.Ct. 1444 (1984), 747 F.2d 844 (3d Cir. 1984), *cert. denied*, ____ U.S. ____, 105 S.Ct. 2678 (1985)	1,14
Coca-Cola Co. v. Snow-Crest Beverages, 4 F.Supp. 980 (D.Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947)	15
Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964)	15-16
Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844 (1982)	*passim*
Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964)	15-16
Statutes Cited:	
15 U.S.C. §1125(a)	*passim*
28 U.S.C. §1254	2
28 U.S.C. §1331	2
28 U.S.C. §1338	2
N.J.S.A. §56:4-1	2
N.J.S.A. §56:8-2	2
United States Constitution Cited:	
Article I, §8, Clause 8	2
Article VI, Par. 2	2
Other Authorities Cited:	
Plevan & Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. Law J. Aug. 12, 1985	9, 12

APPENDIX

Page

Appendix A -
Opinion of the United States Court of Appeals for Third Circuit, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-5689 (3d Cir. May 29, 1985) A-1

Appendix B -
Order of the United States Court of Appeals for the Third Circuit, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-5689 (3d Cir. June 25, 1985) A-6

Appendix C -
Judgment of the United States Court of Appeals for the Third Circuit, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-5689 (3d Cir. July 3, 1985) A-7

Appendix D -
Bench Opinion of the United States District Court for the District of New Jersey, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-1559 (D.N.J. Sept. 5, 1984) A-9

Appendix E -
Order of the United States District Court for the District of New Jersey, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-1559 (D.N.J. Sept. 26, 1984) A-23

Appendix F -
Order of the United States District Court for the District of New Jersey, *Merck & Co., Inc. v. Par Pharmaceutical, Inc.*, No. 84-1559 (D.N.J. Sept. 25, 1984) A-24

Page

Appendix G -
Judgment of the United States District Court for the District of New Jersey, *Merck & Co., Inc. v. Far Pharmaceutical, Inc.*, No. 84-1559 (D.N.J. Sept. 25, 1984) A-27

Appendix H -
Article 1, §8, Clause 8 of the Constitution of the United States A-30

Appendix H -
Article VI, Par. 2 of the Constitution of the United States A-30

Appendix H -
Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a) A-30

Appendix H -
N.J.S.A. Section 56:4-1 ..... A-31

Appendix H -
N.J.S.A. Seciton 56:8-2 ..... A-31

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit, dated May 29, 1985, affirming the judgment of the district court, is not officially reported and is set forth in Appendix A. The order of the Court of Appeals, dated June 25, 1985, denying petitioner's request for rehearing is set forth in Appendix B. The judgment of the Court of Appeals, entered on July 3, 1985, subsequent to the denial of the petitioner's request for rehearing, is set forth in Appendix C.

The bench opinion of the district court, dated September 5, 1984, granting respondent's request for preliminary injunctive relief, is not officially reported and is set forth in Appendix D. The order modifying the bench opinion of the district court, dated September 26, 1984, is set forth in Appendix E. The order for preliminary and final injunction, dated September 25, 1984, is set forth in Appendix F. The final judgment and order of the district court, dated September 25, 1984, is set forth in Appendix G.

JURISDICTION

The judgment of the United States Court of Appeals for the Third Circuit was entered on May 29, 1985. Petitioner's subsequent petition for rehearing was denied on June 25, 1985. The judgment of the Third Circuit was thereafter entered on July 3, 1985.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1). The jurisdiction of the district court was based upon 28 U.S.C. §§1331 and 1338.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 and Article VI, par. 2 of the Constitution of the United States. The federal statutory provision involved herein is §43(a) of the Lanham Act, 15 U.S.C. §1125(a). The state statutory provisions involved herein are New Jersey Statutes Annotated Sections 56:4-1 and 56:8-2.

Due to the length of these provisions, they are set forth in Appendix H.

STATEMENT OF THE CASE

This petition brings before the Court the continuing controversy over the right of generic pharmaceutical manufacturers to make available their products in the appearance to which patients and health care professionals are accustomed.

Since the decision of this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), so-called brand-name drug manufacturers have chosen the U.S. District Court for the District of New Jersey and the Third Circuit as the forum of choice for obtaining injunctive relief against use by generic manufacturers of the same size, shape and color for generic drugs as the brand-name counterparts. In these cases, the courts have either granted the injunctive relief sought, or the defendant obtained a settlement to avoid burdensome litigation.[1]

Unfortunately, the situation arising in the Third Circuit is having a nationwide, uniform effect on the pharmaceutical industry and the delivery of generic drugs to the public. Despite the passage in all fifty states and the District of Columbia of generic substitution laws, the courts below have short-circuited these laws and the *Inwood* decision on a national basis. The reason, simply, is that the pharmaceutical industry is concentrated in the state of New Jersey, including both brand name and generic houses.[2]

---

[1] Other than the instant case, these include *CIBA-Geigy Corp. v. Lemmon Co., Zenith Laboratories, Inc., Danbury Pharmacal, Inc., Chelsea Laboratories, Inc., Par Pharmaceutical, Inc. and Barr Laboratories*, No. 82-670 (D.N.J.) (settled); *CIBA-Geigy Corp. v. Zenith Laboratories, Inc., Bolar Pharmaceutical Co., Inc., Danbury Pharmacal, Inc., and Chelsea Laboratories, Inc.*, No. 82-671 (D.N.J.) (Consent Judgments except as to Bolar); *CIBA-Geigy Corp. v. Bolar Pharmaceutical, Inc.*, 547 F.Supp. 1095 (D.N.J. 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983), *cert. denied*, ____ U.S. ____, 1094 S.Ct. 1444 (1984); 747 F.2d 844 (3d Cir. 1984), *cert denied*, ____ U.S. ____, 105 S.Ct. 2678 (1985) (entry of preliminary and permanent injunctive relief); *Hoffmann-LaRoche, Inc. v. Danbury Pharmacal, Inc.*, No. 83-4922 (D.N.J.) (Consent Judgment); *CIBA-Geigy Corp. v. Zenith Laboratories, Inc.*, No. 83-4928 (D.N.J.) (Consent Judgment); *Sandoz, Inc. v. Par Pharmaceutical, Inc.*, No. 84-0335 (D.N.J.) (Consent Judgment following entry of temporary restraining order); *Eli Lilly and Company v. Barr Laboratories, Inc.*, No. 85-3110 (Consent Judgment following entry of temporary restraining order).

[2] Brand-name houses include American Cyanamid, CIBA-Geigy Corp., Hoechst-Roussell Pharmaceuticals, Hoffmann-LaRoche, Johnson & Johnson, Merck, Sandoz, Schering, and Squibb. Generic companies include Ambix, Barr, Biocraft, Carnrick, Chelsea, Faraday, Heather, Lemmon, Par, Private Formulations, West-Ward, and Zenith.

Since *Inwood*, the courts in the Third Circuit have seized upon various devices to impose liability upon the generic companies. Neither traditional notions of unfair competition, nor the express standards of this Court, appear to pose a serious obstacle to these decisions.

The burden of litigation and the result-orientation in the Third Circuit have made financially impossible, and quixotic, the ability of generic companies to avail themselves of the ambit of protection for imitation afforded by *Inwood v. Ives*. This will foreclose the continuation of the traditional practice of providing generic drugs in the appearance to which patients, pharmacists, and nurses are accustomed. These rules of unfair competition being applied in the Third Circuit contravene the letter and spirit of this Court's decision in *Inwood*, and undermine the state policies encouraging generic substitution. In fact, they effectively grant a monopoly of color in perpetuity after the seventeen-year product patent monopoly has expired.

This case is particularly suited to resolution by this Court. For the first time, a district court in New Jersey has expressly found that there are legitimate advantages to imitation by a generic drug company and legitimate benefits to consumers. In applying its rule of law, the court, however, held that these advantages do not establish functionality. Such a decision makes it possible for this Court to provide meaningful guidance to the entire industry and to the lower courts, as well as to address the underlying public interest in removing artificial federal obstacles to the effectiveness of state laws of generic substitution.

Respondent Merck & Co., Inc. ("Merck") is the manufacturer of a medicine generally known as INDOCIN. INDOCIN, the brand-name of a substance known pharmaceutically as indomethacin, has been marketed for approximately twenty years as useful in the treatment of arthritis and related conditions. Its typical consumer tends to be elderly, and uses the drug on a repeated basis for the chronic disease. Traditionally, refills of INDOCIN have accounted for at least as many sales as new prescriptions for INDOCIN.

Since its initial marketing, INDOCIN has been sold with a blue and white capsule. Various markings currently appear on the blue/white capsule; the white portion of the capsule bears the word "INDOCIN" and the blue half (the cap) bears the letters "MSD" plus either the number 25 or 50. The numbers are apparently intended to show the dosage strength. At no time during the marketing of INDOCIN has the word "Merck" appeared on the capsule, and the word "INDOCIN" did not appear on the capsule until 1981.

INDOCIN, like almost every brand name drug, was subject to a patent during most of its marketing life. The patent expired in late 1981, and was soon followed by various applications to the U.S. Food and Drug Administration ("FDA") by generic manufacturers for approval to market generic indomethacin.

Following the decision in June of 1982 of this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), and in light of other factors, including traditional industry practice, and the pattern of indomethacin use by the elderly for the chronic disease arthritis, Par Pharmaceutical, Inc. ("Par") in July of 1982 filed its application to the FDA for the marketing of indomethacin in the colors blue and white. The application included as part of the trade dress the Par logo in two places on each capsule.

The label for the container of Par's product bore the color brown, where Merck had been using blue labels, and the Par label included the Par logo prominently and conspicuously displayed at the top of the front panel. The general presentation of the Par container was dissimilar from the Merck container. In light of these facts, Merck was able to show no instance of any mistake or confusion with respect to the dispensing of generic indomethacin. Moreover, Merck presented not one instance of illegal substitution or trademark infringement concerning INDOCIN.

Under the relevant standards in *Inwood* of functionality, Par adduced uncontradicted proof of four areas in which trade dress serves a purpose other than identification of source. On these

points, there was unanimity among the experts. These experts included a physician ostensibly appearing for Merck and the only non-employee offered by Merck; the Director of Nursing at the Teaneck, New Jersey Nursing Home; the Director of Nursing at the Troy Hills, New Jersey Nursing Home; and a pharmacist with over twenty years of experience operating retail drug stores.

The experts testified that the trade dress of a branded prescription drug:

1) Identifies for the patient at the time of dispensing the type of medication in terms of its therapeutic effect. These experts testified that patients, when presented with a generic substitute in an unfamiliar color, become confused by the change in color, believing that the wrong medication had been dispensed;

2) Assists patients, particularly the elderly, to adhere to a schedule of ingestion when such patients are taking multiple medications. Many such patients co-mingle their medications in a single container and are able to distinguish among the medications because of their familiarity with the physical appearance of those medications;

3) Assists health care professionals in dispensing the proper medication;[3] and

4) Assists health care professionals to identify medication in emergency situations.

The evidence also showed that Merck investigated for over twenty years the functionality of color and has during that period incorporated the conclusions of its investigation into its color selection process. For example, internal Merck documents

---

[3] In his concurring opinion in *Inwood*, Mr. Justice White observed that these advantages establish the functionality of trade dress at every stage of distribution. See discussion at page 11, *infra*.

from the early 1960's, which documents were routed to the individuals who chose the colors for INDOCIN, identified blue as a "cool" and "sedat[ing]" color. INDOCIN, coincidence or not, is a blue-colored drug intended to have a sedating-type effect on arthritic pain.

More recently, Merck's internal investigations have taken a new and more significant direction. In 1981, Merck commenced an investigation at the top level of management into the effect of physical appearance on substitution rates. Merck adopted as the premise for further investigation the fact that patients would be "upset if an unfamiliar pill was substituted for a familiar one."

As part of its further investigation, Merck reviewed the substitution rates of over sixty types of drugs which were available from multiple sources, *i.e.*, brand name manufacturer and generic companies. Merck concluded that the unavailability of imitative generics caused an average decrease in the generic market of over 40%. Merck further recommended as part of a "strategy to minimize the impact of generic competition ..." that it should try to create appearance distinctions between its products and generic competitors, based upon the conclusions of the study.[4]

On the face of the record below, the district court found that Par had "established" that:

1) imitation of trade dress provides a means of reassuring patients that they are receiving the right medication;

2) that imitation of trade dress assists patients who commingle their medications to adhere to their schedule of ingestion; and

3) that imitative trade dress assists health care professionals to dispense the correct medications. A-18[5]

---

[4] It may be noted that this quality of evidence on the functionality of prescription drug colors was not even available in *Inwood*.

[5] These findings matched three of the four findings of the district court in *Inwood*.

The handling of this overwhelming evidence in the lower court raises serious questions of law. Under the rule of law expressed in *Inwood*, these findings established functionality. Par should have at that point prevailed. However, the district court, as affirmed by the Third District, applied a different rule; a rule contradictory to *Inwood*. According to the district court, the established, legitimate advantages of using blue and white for Par's capsules did not establish functionality because "[a]ny functional uses of the blue and white color scheme were not sufficiently substantial to preclude this competition from entering the market place." A-19. According to the district court, "I do not believe that *Inwood v. Ives* constitutes a ruling on functionality under either Section 32 or Section 43(a)..." A-20.

The district court also held that Par was liable under New Jersey state law because it reasonably anticipated passing off by others. The court referred to no instance of passing off, and no elements of the offense than "reasonable anticipation" of passing off.

On appeal, the Third Circuit affirmed. It affirmed the finding of non-functionality. It also explicitly affirmed the "reasonable anticipation" theory of liability:

> "Merck need only prove that 'a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.' " A-4.

Par petitioned the Third Circuit for rehearing. In its petition, Par argued that the district court had applied a rule of law contrary to *Inwood*. Par specifically argued that the findings of legitimate advantages for imitation compelled a finding of functionality under the rule of *Inwood*. Par further expressed its belief that the majority opinion of the Court in *Inwood* as well as Mr. Justice White's opinion had put to rest the "reasonable anticipation" theory of liability, and that the Third

Circuit's use of such a standard was improper. This request was denied.[6]

In light of the rules in the Third Circuit governing the appearance of generic drugs, Par shares the view of a recent commentator that the pattern of these decisions deserves intervention by this Court:

> "Manufacturers of branded prescription drugs appear to have staked out district courts in the 3d U.S. Circuit Court of Appeals as the courts of choice for lawsuits challenging the sale of 'look-alike' generic drugs. In several recent cases, the 3d Circuit has consistently sided with the brand manufacturers."
>
> * * *
>
> "One can only hope that the Supreme Court soon will again take an interest in these issues and articulate standards that will lend some predictability to this area of the law." Plevan and Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. Law J. Aug. 12, 1985 at 22.

REASONS FOR GRANTING THE WRIT

I. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE CONFLICT BETWEEN THE STANDARD OF FUNCTIONALITY IN *INWOOD v. IVES* AND THE NEW RULE OF FUNCTIONALITY IN THE THIRD CIRCUIT

In the courts below, there were factual findings almost identical to the findings in *Inwood*. The district court found that Par's use of blue and white capsules for indomethacin had three

---

[6] The petition for rehearing also requested the Third Circuit to correct three errors in its factual references to the record. The order denying the petition made no reference to these proposed corrections of the record references. A-6.

legitimate advantages – (1) to help assure patients that they are getting the correct medication; (2) to assist patients who commingle their medications to identify which medicine to take at the proper time; and (3) to assist health care professionals in dispensing the correct medication.

Under *Inwood*, there should have been a finding of functionality. In *Inwood*, the district court likewise made these three findings [7] and this Court held that it was not clearly erroneous for the district court to hold that these advantages constituted functionality.[8]

The court below, however, applied a different rule. It announced a new rule that a trade feature is not functional, as a matter of law, if other companies were able to enter the market without imitating that feature, even if there are legitimate reasons to imitate.

Par respectfully believes that such a new definition of functionality is directly contrary to *Inwood* and an undesirable proposition of the law of unfair competition.

In *Inwood*, the brand-name company made exactly the same argument. There, the evidence in the record showed that other companies had entered the market in that product without using the familiar colors of the CYCLOSPASMOL product. If, in fact, functionality includes as part of its definition an element of proof on the inability of others to compete without imitating, the district court in *Inwood* would have been wrong. There would have been no functionality. This Court, however, held that the district court was not clearly erroneous. In effect, this Court rejected the "barrier to market entry" definition of functionality.

---

[7] The district court here found that he was not "persuaded" that imitation "materially assists" the doctor in emergency identification. A-18.

[8] On remand in *Inwood*, the Second Circuit affirmed the district court's holding that the imitation of Ives' product did not violate Section 43(a) of the Lanham Act, 15 U.S.C. 1125(a).

Par further believes that the ad hoc and incorrect definition of functionality below underscores the need for this Court's intervention. In the various cases involving this overall controversy, the lower courts have reviewed basically the same evidence of functionality and established different results. It is really no longer disputed, even by the brand-name industry, that patients and health care professionals identify the type of medication, rather than its source, based upon its size, shape and color.

The underlying controversy is whether such advantages establish "functionality." The evidence in these cases rarely, if ever, arises from some special characteristics of the particular drug at issue. Rather, the fact of legitimate advantages for trade dress imitation applies across the spectrum of prescription products.

Mr. Justice White in his concurring opinion in *Inwood* quoted a leading commentator on this very point. He wrote:

> "The reality is that for every link in the distributive chain (from producer to ultimate consumer) the color and shape of drugs dispensed by prescription do perform a function. For each of them, color or shape may be a convenient shorthand code by which to identify the drug and its milligram dosage so that mistakes can be avoided in the interests of pharmaceutical precaution and patient safety. For the patient-user, of course, the constancy of color and shape may be as psychologically reassuring and therefore as medically beneficial as the drug itself; in addition; they also serve to identify the drug for his ingestion....
>
> "(I)f the generic producer is constrained by §43(a), the trademark law, or the law of unfair competition to adopt a substantially different color... the therapeutic value of his generic drug might be seriously impaired and confusion at the pharmacist level could be compounded beyond redemption. 3R Callmann, Unfair Competition, Trademarks and Monopolies §82.1 (m), pp 217, 213 (Supp 1981)." *Inwood*, 456 U.S. at 862 n.3

Another observer has specifically noted that this issue of "functionality" presents sufficient legal questions for this Court to resolve:

> "At first blush, the issues of functionality and secondary meaning appear to be too fact-bound to merit Supreme Court attention. The facts giving rise to these and other look-alike drug cases, however, are so similar and have arisen so frequently that there should be no impediment to the Supreme Court resolving many of the dispositive issues as a matter of law. For example, regarding proof of functionality, it was conceded in both *Ives* and *Bolar* that the plaintiffs' initial choice of colors for its products was arbitrary and fanciful. Yet, after the drugs had been on the market for several years, the colors have acquired certain significance to customers. Whether colors could become functional after a period of time is a question addressed in both cases, yet the courts reached opposite conclusions on the basis of identical indicia of functionality, such as the anxiety of elderly patients receiving unfamiliar drugs." Plevan & Siroky, National Law Journal, *supra*.[9]

The large and still-growing body of evidence about the market of prescription drugs continues to show that, absent special circumstances, the use of familiar product appearances by generic companies does not mislead the public, but rather improves patient compliance and assists in the safe dispensing and ingestion of such drugs.

In the light of the findings by the district court of legitimate reasons for Par to use the same size, shape and color capsules as Merck, this case presents an appropriate opportunity for this

---

[9] Par further believes that the Third Circuit standard of secondary meaning in these cases is wrong. In the unique prescription drug area, advertising is directed at professionals, not patients. Thus advertising is a poor indicia of consumer belief. Likewise, it is paradoxical to regard the act of imitation as an indicia of secondary meaning where there are legitimate reasons to imitate.

Court to reaffirm the vitality of *Inwood*. In so doing, the Court can correct the standard of law now applied in the Third Circuit and remove a major barrier to effective delivery to the public of low-priced generic drugs. Par believes that certain lower courts should not be free to ignore *Inwood* simply because they disagree with its outcome.

II. CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE STANDARD OF CONTRIBUTORY LIABILITY BASED UPON "REASONABLE ANTICIPATION" CAN SURVIVE AFTER *INWOOD v. IVES*

In *Inwood*, the source of greatest controversy among the parties was whether "reasonable anticipation" alone could provide a sufficient basis for imposing liability upon a manufacturer. The Court rejected the rule of "reasonable anticipation". The majority described the "reasonable anticipation" theory as " 'watered-down' and incorrect." 456 U.S. at 854 n.13. In his concurring opinion, Mr. Justice White vigorously discussed and criticized the "reasonable anticipation" standard. 456 U.S. at 861-62.

The Third Circuit, however, has continued to expressly apply this standard. In the decision below, the Third Circuit held that:

> "For its New Jersey passing off claim, Merck need only prove that 'a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off. *Ciba-Geigy*, 747 F.2d 844, 852 (3d Cir. 1984) (*citing SK&F*, 625 F.2d at 1062)." A-4.

One may note at the outset that no such standard actually exists in any New Jersey statute or case law. As stated succintly by Judge Giles in dissent in another post-*Inwood* decision of the Third Circuit:

"Nothing in the 'general tenants' of New Jersey unfair competition law, as articulated by the *Merrell* court, tends to prove that New Jersey would adopt the reasonable anticipation standard over the test of intentional inducement. Indeed, the SK&F court's acknowledgment that New Jersey follows sections 711 and 713 of the Restatement (First) of Torts would indicate the exact opposite. The only insight provided by New Jersey courts is found in dicta in the *French American Reeds* case. The Superior Court of New Jersey noted that the action did not present questions of passing off or 'fraudulent marketing,' citing the Restatement (First) of Torts §711(1938). Quoting plaintiff, the court stated that the claim did 'not involve any element of actual intent or any attempt on respondents' part to see their goods as those of appellant.' *French American Reeds*, 20 N.J. Super. at 329, 90 A.2d at 52. If reasonable anticipation were the standard in New Jersey, the plaintiff in *French American Reeds* might not have limited the case to claims of unprivileged imitation.

"Discounting the so-called 'general tenants' of unfair competition, the *Merrell* decision, upon which the SK&F court relied, is based upon an analogy to federal law. This analogy is not longer justified in the wake of Ives. Assuming the reasonable anticipation standard has been overruled as a matter of federal law, it follows that it cannot be viable under New Jersey law in the absence of any endorsement of that standard by the court of New Jersey." [11] *CIBA-Geigy v. Bolar*, 747 F.2d at 863.

---

[11] Given the continued prohibition against imitation under Section 43(a) where there is no act of inducement of passing off by the manufacturer, the Third Circuit is also implicitly using a "reasonable anticipation standard" under federal law.

Assuming, however, that such a rule exists, it cannot stand. The intolerable effect of the rule is to completely prohibit trade dress imitation under the rubric of New Jersey Law, because anyone in business can expect some unknown bad actors to engage in passing off. As Judge Wyzanski wrote:

> "Any man of common sense knows that in any line of business...there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from the one they ordered." *Coca-Cola Co. v. Snow Crest Beverages*, 64 F. Supp. 980, 989 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert denied*, 332 U.S. 809 (1947).

In *Sears-Compco*, this Court described the circumstances under which state law could not impose liability. It held that a state could not enjoin imitation itself, absent a patent, but only require disclosure of the source of the product. What *Sears-Compco* said a state could not do is exactly what the state law applied below does:

> "As we have said in Sears, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied from an unpatented article could be made in some other way, that the design is 'nonfunctional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article

> is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling, however, and *regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling, Cf. Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120, 59 S.Ct. 109, 114, 83 L.Ed. 73 (1938). And of course a State cannot hold a copier accountable in damages for failure to label or otherwise to identify his goods unless his failure is in violation of valid state statutory or decisional law requiring the copier to label or take other precautions to prevent confusion of customers as to the source of the goods." *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S., 234, 238-39 (1964). [emphasis added] *See also Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964).[12]

As a matter of policy, Par also believes that the supposed view of New Jersey law is unwise. The pharmaceutical industry is national, if not international, in scope. Patient care is a national issue. Hence, the delivery of prescription drugs involves a national system. In this regard, in a very brief period every single state has passed generic substitution laws which are designed to deliver to the public generic drugs at reasonable prices below the monopoly price structure charged by brand-name companies during and after patent life.

The supposed rule of New Jersey law creates the unusual situation where what is lawful imitation elsewhere is unlawful in New Jersey. Such a rule would compel generic drug manufacturers to refrain from imitation on all its products, and thereby

---

[12] There is no evidence that pharmacists are, as a class, less honest than any other group of people. Thus, it is particularly undesirable to permit a ban on copying in the prescription drug field. where there are legitimate reasons to imitiate.

forego delivering the acknowledged benefits of imitation to every patient and health care professional in the country, solely because of New Jersey state law; or to manufacture a separate product for sale in New Jersey. The costs of maintaining separate production, inventory and distribution control systems under the latter alternative would be so expensive as to jeopardize the very purpose of generic drugs in the health care system.[13]

The rule of "reasonable anticipation" as applied by the Third Circuit would effectively end the ability of generic pharmaceutical companies to provide products in the size, shape, and color to which patients and professionals are accustomed. This consequence, if permitted by the Court to continue, would interfere with the policy of all fifty states and the District of Columbia. Par respectfully believes that a federal court such as the Third Circuit may not properly invoke a non-existent doctrine of state law and apply such a doctrine in order to prohibit that which is encouraged by all state laws, and permitted by federal law.

---

[13] Par, like many other generic manufacturers, would not even be guaranteed this choice by the Third Circuit, since it is located in New Jersey.

CONCLUSION

It is respectfully requested that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

Of Counsel
LAWRENCE H. ROTH

APPENDIX

APPENDIX A

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-5689 (3d Cir. May 29, 1985)

United States Court of Appeals

for the

Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation,

Appellee,

vs.

PAR PHARMACEUTICAL, INC.,
a New Jersey Corporation,

Appellant.

Appeal From the United States District Court
For the District of New Jersey - Newark
D.C. Civil No. 84-1559
District Judge: Honorable Dickinson R. Debevoise

Argued May 16, 1985

Before: HUNTER, SLOVITER, *Circuit Judges*, and MUIR,* *District Judge*

Opinion filed May 29, 1985

*Honorable Malcolm Muir, United States District Judge for the Middle District of Pennsylvania, sitting by designation

MEMORANDUM OPINION OF THE COURT

HUNTER, *Circuit Judge:*

1. Appellant Par Pharmaceutical, Inc. ("Par") appeals the judgment of the District Court for the District of New Jersey permanently enjoining them from marketing a drug called indomethacin in a trade dress virtually identical to that of Merck & Co., Inc. ("Merck").

2. Appellee Merck is a pharmaceutical company in New Jersey well known for its research, development, manufacture and distribution of drugs. The Merck laboratories discovered indomethacin in 1959, a drug which is used as an anti-inflammatory in treating the symptoms of ailments such as arthritis, ankylosing spondylitis, gouty arthritis, bursitis and tendonitis. Merck has marketed indomethacin under the trade name of "Indocin" since 1965 in a hard, opaque, blue and white capsule and has been highly successful. Merck held a patent on indomethacin until it expired on December 15, 1981. At that time the FDA approved four generic firms in the United States to market indomethacin, but none of these companies chose to dress the capsules in the Merck blue and white. The generic firms began to market indomethacin in 1984 at prices 18 to 20 percent below that of Merck. By mid-July 1984 more than 50 percent of all indomethacin prescriptions were being filled with generic indomethacin.

3. Par, another generic drug manufacturer, submitted a New Drug Application to the FDA in 1982, seeking approval for their version of indomethacin. In their application, Par specified that they planned to put the drug in blue and white capsules almost identical to those of Merck, with their name, "PAR" in black letters. On its blue and white capsules, Merck has printed "MSD" in letters of the same size and shape.

4. Par's President, Perry Levine, testified in his deposition that he decided on the blue and white configuration for the capsules, so strikingly similar to the trade dress of Indocin, because he felt that Par's drug would be more easily accepted in the

marketplace if it looked like Indocin. The district court found, as an additional reason for Par's selection of the blue and white capsules the effort "to obtain a competitive advantage over competing generic manufacturers who had selected other colors."

5. When Merck discovered that Par had a substantial inventory of the product ready to be shipped when FDA clearance was obtained, and intended to market its version of indomethacin in the same trade dress as Merck, it brought an immediate action for a preliminary injunction. Merck claims it is entitled to an injunction under section 43(a) of the Lanham Act, 15 U.S.C. §1125(a) (1982) and New Jersey statutory and common law proscriptions on "passing off" and "unprivileged imitation." After some initial discovery procedures, Merck learned that Par had indeed obtained FDA approval, had in fact shipped approximately nine million blue and white indomethacin capsules and had outstanding unfilled orders for many more. Merck then applied for a temporary restraining order prohibiting Par from shipping or distributing indomethacin in Merck's trade dress. The district court granted Merck's application on August 13, 1984. On September 4, 1984, the district court entered a bench opinion with findings of fact and conclusions of law ruling that Merck had fulfilled the requirements for a preliminary injunction. Par and Merck then submitted documents to the district court in order to allow it to convert the prelimary injunction into a permanent injunction, appropriate to effect a final, appealable order. The district court entered a final judgment on September 25, 1984, finding that Merck had established its claims of passing off and unprivileged imitation under New Jersey law and its section 43(a) claim under the Lanham Act. The court adopted its findings and conclusions as final based upon the record before the court at the time of the decision on the preliminary injunction. It entered a permanent injunction prohibiting Par from selling indomethacin in blue and white capsules so similar to those of Merck.

6. The district court ruled in favor of Merck based primarily on *SK&F, Co. v. Premo Pharmaceutical Lab.*, 625 F.2d 1055

(3d Cir. 1980), a case similar to this one. There, this court upheld a district court preliminary injunction which prohibited a generic drug manufacturer from marketing a drug containing an oral diuretic in hard gelatin capsules having the same maroon and white color combination as the capsules used in marketing the plaintiff's similar product. As here, the plaintiff in *SK&F*, alleged violations of the New Jersey passing off and unprivileged imitation statutes and the Lanham Act, section 43(a). But what more strikingly compels us to uphold the district court's injunction is that after the district court in the case before us here had issued its opinion, our court decided another trade dress case, *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.*, 747 F.2d 844 (3d Cir. 1984). In *Ciba-Geigy*, as here, the district court transformed a preliminary injunction into a permanent injunction. We upheld the permanent injunction against a generic drug manufacturer, prohibiting it from distributing a drug in the same trade dress as that of the plaintiff pharmaceutical company.

7. Under both *Ciba-Geigy* and *SK&F*, this court set out the standards for establishing a claim under the New Jersey passing off and unprivileged imitation laws, as well as section 43(a) of the Lanham Act. For its New Jersey passing off claim, Merck need only prove that "a drug manufacturer ... put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off." *Ciba-Geigy*, 747 F.2d 844, 852 (3d Cir. 1984) (*citing SK&F*, 625 F.2d at 1062). The district court here found that Merck had succeeded in proving that Par could reasonably anticipate that pharmacists would illegally substitute its drug for that of Merck. We cannot say that the district court's finding was clearly erroneous.

8. To establish a claim for unprivileged imitation under New Jersey law, Merck must show "(a) that an imitated feature of its product is non-functional, (2) that the imitation is likely to cause confusion as to the product's origin, and (3) that the product has acquired secondary meaning." *Ciba-Geigy Corp. v.*

Bolar Pharmaceutical Co., 747 F.2d 844, 850 (3d Cir. 1984).[1] The district court in the case before us, faced almost identical contentions of functionality and found, as a matter of fact,[2] that the blue and white trade dress was non-functional. It also found that the imitation was likely to cause confusion and that Merck's blue and white capsules had acquired secondary meaning denoting a common source. We cannot say that any one of these findings by the district court was clearly erroneous.

9. The decision in *Ciba-Geigy* controls our disposition of Merck's federal cause of action under the Lanham Act as well. "To establish unprivileged imitation under the Act, a plaintiff must prove the non-functionality of the imitated feature and prove secondary meaning of the imitated feature. These proofs are essentially the same as those required for unprivileged imitation under New Jersey law." *Ciba-Geigy*, 747 F.2d at 854. The district court's findings here as to functionality and secondary meaning are not clearly erroneous. Therefore, as we held in *Ciba-Geigy*, those findings establish the validity of the federal claim as well.

10. Accordingly, the judgment of the district court will be affirmed.

TO THE CLERK

Please file the foregoing opinion.

JAMES HUNTER, III, *Circuit Judge*

---

[1] The Supreme Court in *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844, 850-51 (1982), defined both functionality and secondary meaning. The Court said there that "a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." *Id.* at 850. "To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of the product feature or term is to identify the source of the product rather than the product itself." *Id.* at 851.

[2] *See Ciba-Geigy*, 747 F.2d at 850 (court's finding on functionality is finding of fact).

APPENDIX B

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-5689 (3d Cir. June 25, 1985)

United States Court of Appeals
for the
Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation,
Appellee,

vs.

PAR PHARMACEUTICAL, INC., a New Jersey Corporation,
Appellant.

SUR PETITION FOR REHEARING

Present: ALDISERT, *Chief Judge*, SEITZ, GIBBONS, HUNTER, WEIS, GARTH, SLOVITER, BECKER, STAPLETON and MANSMANN, *Circuit Judges*

The petition for rehearing filed by

APPELLANT

in the above entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

By the Court,

s/James Hunter
Judge

Dated: June 25, 1985

APPENDIX C

JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, *MERCK & CO., INC. V. PAR PHARMACEUTICAL, INC.*, No. 84-5689 (3d Cir. July 3, 1985)

United States Court of Appeals

for the

Third Circuit

No. 84-5689

MERCK & CO., INC., a New Jersey Corporation

Appellee

vs.

PAR PHARMACEUTICAL, INC., a New Jersey Corporation

Appellant

Appeal From the United States District Court
For the District of New Jersey - Newark
D.C. Civil No. 84-1559
District Judge: Honorable Dickinson R. Debevoise

Before: HUNTER, SLOVITER, *Circuit Judges*, and MUIR,* *District Judge*

JUDGMENT

This cause came to be heard on the record from the United States District Court for the District of New Jersey and was argued May 16, 1985.

* Honorable Malcolm Muir, United States District Judge for the Middle District of Pennsylvania, sitting by designation.

On consideration whereof, it is now ordered and adjudged by this Court that the order of the District Court entered September 25, 1984 be, and the same is hereby, affirmed.

Costs taxed against appellant.

ATTEST:

Clerk

May 29, 1985

Certified as a true copy and issued in lieu
of a formal mandate on July 3, 1985.

Test:

Chief Deputy Clerk, United States Court of Appeals
for the Third Circuit.

APPENDIX D

OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW JERSEY, *MERCK & COMPANY, INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. Sept. 5, 1984)

United States District Court

for the

District of New Jersey

Civil Action No. 84-1559

MERCK & COMPANY, INC., a New Jersey corporation,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC., a New Jersey corporation,

Defendant.

TRANSCRIPT OF PROCEEDINGS

Newark, New Jersey
September 5, 1984

BEFORE:

HONORABLE DICKINSON R. DEBEVOISE, U.S.D.J.

Appearances:

SHANLEY & FISHER, ESQS.
BY: RONALD GOULD, ESQ.
Attorneys for the Plaintiff

LAWRENCE H. ROTH, ESQ. (NY)
Attorney for the Defendant

THE COURT: I'm going to put an opinion on the record reserving the opportunity to go over it and make any corrections after it has been initially typed. Then it can be distributed to the parties and filed with the Court.

Plaintiff, Merck & Co., Inc., instituted this action against defendant, Par Pharmaceutical, Inc., charging false designation of origin and false description or representation of goods in violation of Section 43(a) of the Lanham Act, 15 U.S.C. Section 1125(a). In addition, Merck charges unfair competition in violation of New Jersey's statutory and common law.

Since 1965 Merck has manufactured and distributed the prescription drug indomethacin under its registered trademark INDOCIN. Merck's patent on the drug expired and a number of companies, as they are entitled to do, commenced selling the generic drug. Par is one of these companies. In this suit Merck challenges the color and shape of the indomethacin pills which Par intends to distribute. When Merck learned that distribution of the pills was imminent it sought a temporary restraining order and preliminary injunction. After a hearing I granted the temporary restraining order and scheduled a hearing on the application for preliminary injunction. Extensive affidavits, depositions and exhibits have been filed.

A hearing has been held at which additional argument was given. Neither side sought to call witnesses. This constitutes my findings of fact and conclusions of law.

THE FACTS

Merck is a New Jersey corporation having its principal place of business in this state. It is well known for its work in research, development, manufacture and distribution of pharmaceutical products. Indomethacin was discovered in the Merck laboratories in 1959 and thereafter was approved by the United States Food & Drug Administration for treating certain ailments. It is a prescription pharmaceutical dispensed by retail pharmacists only upon the prescription of a physician. Merck sells it under its trademark Indocin.

Since 1965, Merck has manufactured and distributed the prescription drug indomethacin in capsule form for oral administration to human patients for use as an anti-inflammatory agent. Indomethacin in is a highly successful therapeutic agent in the field of human rheumatoid arthritis, ankylosing spondylitis, gouty arthritis, osteoarthritis, bursitis and/or tendonitis.

Indomethacin has been prepared for sale to the ultimate consumer (the patient for whom it is prescribed) in hard gelatin capsules. The capsules bear the following logos:

25 milligram capsule: MSD

25

50 milligram capsule: MSD

50

Both the 25 milligram capsule and the 50 milligram capsule are opaque, blue and white, and in some cases the printing thereon is vertical, and in some instances, horizontal. Commencing in 1981 the trademark INDOCIN has also been printed on the capsules. The capsules are standard No. 1 and No. 3 capsules. The 25 milligram indomethacin capsule was introduced on the market on June 21, 1965 and the 50 milligram capsule was introduced April 26, 1968. Since 1965 when Merck introduced indomethacin until Par introduced its product, there had been no other product containing indomethacin as an active ingredient marketed in the United States as a prescription medication in the same combinations of colors, sizes and shapes as Merck's indomethacin.

Annual sales of INDOCIN increased from $11,537,000 in 1965 to $98,201,000 in 1983. Patients for whom indomethacin was prescribed were likely to use it over extended periods of time. Merck has engaged in extensive nationwide advertising and promotion of its indomethacin product. Total expenditures for these

purposes for the years 1965 through 1983 have exceeded $75,000,000. A major portion of its material is directed to physicians and druggists. Some is carried in journals read both by professionals and laymen. Some is contained in books on prescription drugs prepared for laymen. The colors, sizes and shapes of Merck's indomethacin capsules have been featured in its advertising and promotion and serve to identify both the product and the source, namely, Merck.

On the basis of the deposition testimony of Douglas M. Durand, Merck's product manager for Indocin, Par attacked Merck's advertising expenditure figures. While there appears to be merit to Par's observations, the advertising expenses were nevertheless very great.

The product patent on indomethacin expired on December 15, 1981. Thereafter four generic firms received FDA approval to market indomethacin in the United States. These firms are Mylan Pharmaceuticals, Inc., which uses green capsules, Lederle Laboratories, which uses pink and white capsules, Chelsea Laboratories, Inc., which uses orange capsules, and Zenith Laboratories, Inc., which uses white capsules.

In the early summer of 1984 the prices of generic indomethacin sold by these firms were 18 percent to 28 percent below the price of Merck's indomethacin. As more firms commence producing the generic drug, the differential is likely to increase. Although the generic products were first approved in late April 1984, by mid-July 1984 more than 50 percent of new prescriptions for indomethacin were being filled with generic products other than Merck's INDOCIN.

Par is a generic drug manufacturer. In July 1982 Par submitted a New Drug Application to the United States Food & Drug Administration, seeking approval for the marketing of its generic version of indomethacin.

Par specified a blue and white color configuration for its product and included its name "Par" in black letters on its capsule, just as Merck included the identifying letters "MSD" on

its capsules. Par's President, Perry Levine, states he was responsible for selecting the blue and white color configuration. He gives the following rational for his decision to select a trade dress which is strikingly close to the Indocin trade dress: "In order for generic drug products to be accepted in the marketplace by patients, we believe the similarity in appearance insofar as size and shape and color are concerned is an important functional attribute of a medicinal product such as the one involved in this case. If a generic product was *lawfully* dispensed after a patient had been taking a brand name product, the discovery of a different color would ususally be made by the patient at home. I believe, and my belief is supported by the general medical community, that such a patient would suffer much anxiety and confusion if the accustomed medicine were dispensed in a different color, even though they otherwise knew they were supposed to be getting a generic version in place of a brand name product... Of further importance is the fact this the capsule colors assist patients in identifying the appropriate medicine to take at the appropriate time."

I find an additional reason for Par's color selection is to obtain a competitive advantage over competing generic manufacturers of generic indomethacin who selected other colors. It is not without significance that one of Par's potential customers solicited orders for the Par product by describing it in banner letters as "INDOCIN GENERIC LOOK-ALIKE."

In its application for injunctive relief Merck urges that the existence of a generic product which looks like its INDOCIN is an invitation to less than scrupulous or careless pharmacists to substitute the generic product for INDOCIN, when selling to customers, thereby reaping a handsome profit. Par says that it has no interest or intent to promote such illegal acts and has taken steps to prevent such occurences. Its bottles containing the capsules are round, while Merck's are rectangular. The color and layout of its labels differ from Merck's; its name is prominently displayed on the bottles and capsules; the bottles sold to pharmacists include cautionary language on an adhesive sticker attached to the top of the bottle:

> "Notice: This product may be substituted for Indocin only when authorized by law. When dispensing label this product only as INDOMETHACIN."

Par undertakes to stop selling to any pharmacist or other person engaging in any illegal acts involving its product.

On August 6th, 1984 Par received FDA approval to market its indomethacin and on August 7th shipped 9,000,000 capsules. At the time I entered the temporary restraining order there were outstanding unfilled orders for capsules.

CONCLUSIONS OF LAW

The Court has federal question and pendent jurisdiction of this case.

The prerequisites for preliminary injunctive relief in this circuit are (1) a reasonable probability of ultimate success on the merits and (2) irreparable injury during the pendency of the action if the relief is not granted to prevent a change in the status quo. *SK&F Co. against Premo Pharmaceutical Laboratories, Inc.*, 481 F. Supp. 1184 (D.N.J. 1979) *aff'd*, 625 F.2d 1055 (3d. Cir. 1980). Where relevant, the Court should take into account (3) the possibility of harm to other interested parties harmed by the relief and (4) the public interest. *Delaware River Port Authority v. Transamerican Trail Transport, Inc.*, 501 F.2d 917 (3d Cir. 1974).

1. *The Merits*. The case is governed by the Third Circuit opinion in *SK&F Co. v. Premo Pharmaceutical Laboratories, supra*. See also *Ciba-Geigy Corp. v. Bolar Pharmaceutical, Inc.*, 547 F. Supp. 1085 (D.N.J. 1982) *aff'd*, 719 F. Supp. 756 (3d. Cir. 1983), *cert. denied*, 104 S. Ct. 1444 (1984). In *SK&F, supra*, the Third Circuit affirmed the District Court's preliminary injunction order preventing the defendant Premo from marketing a diuretic/hypertensive drug in capsules having the same combination of colors as plaintiff's DYAZIDE product which contained the same drug. The brand name product in the *SK&F* case was introduced by SK&F in 1965 after a long

period of research and development. It was marketed as a powder containing a maroon and white capsule with the brand DYAZIDE and the logo SK&F printed on both the white half and the maroon half of the capsule. SK&F had expended large amounts of money promoting its DYAZIDE product through a network of detail men calling on doctors, hospitals and pharmacies, and also advertised in journals likely to reach the medical profession. Doctors had prescribed DYAZIDE therapy for over 20 million patients, with average therapy extending over the course of the months or years. During this time each patient consumed hundreds of DYAZIDE capsules so as to have noted the arbitrary and distinctive appearance of those capsules.

Premo, the defendant in *SK&F*, was a manufacturer of generic pharmaceuticals. It began to market the generic substitute for DYAZIDE in capsules which utilized the same blue and white color schemes used by SK&F for many years. The Court of Appeals affirmed the District Court's finding that defendant was guilty of two types of unfair competition under New Jersey law: passing off one's goods or services as those of another, and unprivileged imitation.

With respect to "passing off," the court cited an earlier case which specifically held it to be

> actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.

SK&F, 625 F.2d at 1062 (citing, *inter alia*, *Merrel-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157, 159-60. (D.N.J. 1977), *aff'd*, 579 F.2d. 786. (3d Cir. 1978).

The Third Circuit affirmed the District Court's conclusion that SK&F would be likely to succeed at a final hearing on this issue stating:

> As to passing off, it is undisputed that the maroon and white color scheme of a virtually identical capsule container was adopted by Premo with the intention of associating, its product in the mind of users, physicians and pharmacists, with DYAZIDE. It is nowhere suggested that Premo was unaware of the practice by some unscrupulous pharmacists of substituting less expensive generic drugs for the brand name drugs prescribed without informing their customers and without passing along the benefit of the lower price. It was reasonable for the district court to conclude that Premo's use of a practically identical trade dress would facilitate such passing off.

625 F.2d. at 1063.

With respect to the tort of unprivileged imitation, the Court stated that, under New Jersey law, its elements are, conjunctively, secondary meaning and nonfunctionality. A showing must be made that the allegedly nonfunctional element does not enhance efficacy. *Id.* (citing *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F.2d. 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960). SK&F prevailed on this issue as well. The court noted that the adoption of trade dress for the DYAZIDE capsule was arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing, and that its "only value was in identifying the goods with their source, and that value, suffices in the New Jersey courts to establish secondary meaning." As to functionality, the Court noted that an identical combination drug was marketed by a third party in a wholly different tablet form, and that there was ample evidence that neither the capsule form nor the color combination reflects any industry practice for the identification of diuretics. 625 F.2d. at 1064.

With respect to the plaintiff's claim under Section 43(a) of the Lanham Act, the Court held that "except for the interstate commerce requirement, the elements of unfair competition torts

prescribed by the New Jersey law and by Section 43(a) of the Lanham Act are the same." 625 F.2d. at 1066. Having found that SK&F had demonstrated a likelihood of success on these claims, it followed that success was likely under Section 43(a).

In the present case Par admittedly sought to make its product look like Merck's Indocin in form, color and size. This similarity is used as a selling point when Par promotes its product among pharmacists. The fact that one potential customer touted Par's product as an "Indocin generic look-alike" is significant. Jeffrey Levine, who oversees Par's sales and service department, testified on deposition that he believes that there are pharamacists who are inclined to substitute generic products illegally. His opinion that Par's label concerning unauthorized substitution for Indocin would deter those otherwise disposed towards illegal activity is unpersuasive. The motive, the opportunity and the inclination by some to substitute the generic drug illegally are all present when Par distributes its look-alike product. In these circumstances I conclude that Merck is likely to succeed on the merits on its New Jersey common law passing off claim.

Similarly, I conclude that Merck is likely to succeed on the merits on its New Jersey common law unprivileged imitation claim.

The evidence strongly supports Merck's position that the particular trade dress of its Indocin product (including its form, color combination, sizes and placement of its identifying letters) has acquired a secondary meaning denoting a common source of the product and denoting to doctors and pharmacists and at least to some patients that Merck was that source. The fact of Par's imitation of the trade dress is significant. By design the Par product is almost indistinguishable from Merck's. Even the designation PAR which is superimposed upon the Par product appears to all but the most observant person to be the same symbol as Merck's MDS which appears on the Indocin capsule. Extensive advertising, varied and substantial sales efforts and commercial success during a 14-year period are further indicia of secondary meaning.

Par urges strenuously that the trade dress serves a functional purpose and that therefore Merck has not established the second prong of its unprivileged imitation claim – non-functionality.

Most of the arguments which Par advances are the same as those urged unsuccessfully in *SK&F* and *Ciba-Geigy*. One is new. On the basis of information which Par developed during discovery, Par asserts that Merck did not select the blue color in an arbitrary and fanciful manner. Rather, on the basis of 1963 research, it determined that color, per se, has a therapeutic value. Reds produce responses which are stimulating and exciting; green produces responses which are calm, peaceful and serene; yellows induce cheerful, jovial and joyful responses; blues induce pleasant, secure, tender and soothing responses. Par argues that Merck selected blue for the response it would produce in patients. Thus, the color has a functional purpose. Apart from the fact that this alleged function served more in the nature of a promotional effect, Par did not simply select the blue color which it asserts has therapeutic qualities. It selected blue and white in the same pattern long used by Merck. There might well be no lawsuit if Par had chosen only the allegedly therapeutic blue color.

The other supposedly functional features of Merck's trade dress are those advanced in the other cases. The evidence in this case and the findings in other cases establish that when a prescription drug used by patients over an extended period of time, is sold in the same time trade dress for many years, the trade dress does, to some extent at least, make it easier for pharmacists and nurses to dispense drugs, provide a way for patients to avoid commingling drugs, and give the patient a feeling of continuity and security. I am not at all persuaded by the evidence that use of look-alike generic drugs materially assists a doctor in dealing with an emergency overdose situation.

I conclude that these advantages which have been established which are to be gained from using the same trade dress for generic drugs as was used for the previously patented drugs are

so minimal that they cannot serve to render the trade dress functional within the meaning of New Jersey law of unprivileged imitation.

Other drugs for use in other fields have the same blue and white color as Indocin. Antiarthritic drugs other than Indocin come in a wide range of colors and shapes. The four other generic indomethacin products which now compete with Indocin are produced in the colors green, pink and white, orange, and white. Any functional uses of the blue and white color scheme were not sufficiently substantial to preclude this competition from entering the market place.

These conclusions relating to the New Jersey common law lead to the further conclusion that Par's conduct also violates Section 43(a) of the Lanham act, 15 U.S.C. Section 1125(a) unless, as Par urges, the case of *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844 (1982) requires a different result. There in circumstances similar to the present case Ives (the manufacturer of the originally patented drug) instituted suit against Inwood, the manufacturer of a look-alike generic drug, under Section 32 and 43(a) of the Lanham Act. After a trial, the District Court found that Inwood's conduct did not violate Section 32 since Inwood had not suggested even by implication that pharmacists could dispense the generic drugs incorrectly as Ives' product.

Ruling on Ives' Section 43(a) claim, the District Court found that the color scheme which Inwood copied was functional for much the same reasons as Par urges in the present case. The District Court also found that Ives' color scheme did not indicate the drug's origin. The Court of Appeals for the Second Circuit concluded that Inwood had violated Section 32 and reversed without reaching Ives' Section 43(a) claim. Upon its review of the Second Circuit decision the Supreme Court reviewed the law concerning contributory infringement in violation of Section 32 and reversed because the Court of Appeals erred in setting aside findings of fact that were not clearly erroneous. The

opinion did not purport to rule on Ives' Section 43(a) claim. The Supreme Court's principal opinion concluded with the statement:

> Although the District Court also dismissed Ives' claims alleging that the petitioners violated Section 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because Section 43(a) prohibits a broader range of practices than does Section 32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

456 U.S. at 858.

Thus, I do not believe that *Inwood v. Ives* constitutes a ruling on functionality under either Section 32 or Section 43(a) and that *SK&F* and *Ciba-Geigy* are still the law on this subject for 43(a) purposes.

It is likely that Merck will prevail on the merits both on its state law claim and on its Section 43(a) claim.

2. *Other Equitable Considerations:*

Turning to the other requirements for injunctive relief, Merck is threatened with irreparable injury. The likelihood of at least some illegal substitution poses a threat of liability for injuries for which Merck should not be responsible. It is threatened with direct monetary loss and injury to its reputation. These injuries often involve imponderables which cannot be translated into ascertainable monetary damages.

As far as Par's is concerned, there was no necessity for it to have adopted a trade dress which mimicked the dress utilized by Merck for more than 14 years. It could have adopted its own distinctive trade dress and built its own reputation as the other

manufacturers of the generic product had done. In behaving as it did it took a calculated risk and having lost it is eminently just that it bear the consequences.

Clearly the public has an interest in the production and sale of generic drugs at the lowest possible prices. But there are countervailing interests. One is in the unmistakable identification of the sources of drugs so that if there are defects in the product those who were responsible for the defects can be held responsible and so that those who are not responsible will not be threatened with undeserved suit. The public has an interest in drug manufacturers building and maintaining reputations for good quality products. The remedies provided under the Lanham Act are means to encourage the building and maintenance of such reputation.

Par urges on the basis of a Merck study that the generic products could obtain a greater share of the market if they could use the same trade dress as Indocin — that, in effect, it could compete more effectively. Judge Gibbons answered that argument, in *SK&F*, stating at page 1067:

> The only answer that Premo made when confronted with these factors was, in essence, that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by *SK&F* for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound or feel of equity. Therefore, the trial court did not err in concluding that the competing equities favored preliminary injunction relief of *SK&F*.

The public has an interest in Par entering into competition in the manufacture and the sale of indomethacin, provided it does so on the strength of its own product sold under its own trade dress. The public does not have an interest in Par entering into such competition using a look-alike product which looks as if it came from another source.

All the conditions for the issuance of a preliminary injunction enjoining Par in the sale and distribution of indomethacin using the Indocin trade dress having been established, an injunction will issue. Merck's attorneys are requested to submit a form of order in accordance with this opinion.

APPENDIX E

ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 26, 1984)

United States District Court

for the

District of New Jersey

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

ORDER

It is this 25th day of September 1984 *ORDERED* that the court's bench opinion in the above matter be corrected as follows:

1. At page 5, line 18 of the transcript the words "fifty percent" shall be changed to read "fifteen percent".

2. At page 13, line 3 and at page 17, line 4 of the transcript the words "fourteen-year" shall be changed to read "nineteen-year".

3. On page 5 at line 11 of the transcript the description of the capsules of Chelsea Laboratories, Inc. as "orange" shall be changed to "yellow for the 25 mg. capsules and blue for the 50 mg. capsules".

DICKINSON R. DEBEVOISE
U.S.D.J.

APPENDIX F

ORDER FOR PRELIMINARY AND FINAL INJUNCTION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 25, 1984)

United States District Court

for the

District of New Jersey

Honorable D. Debevoise

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

ORDER FOR PRELIMINARY AND FINAL INJUNCTION

This matter having been brought before the Court on the application of counsel for Merck & Co., Inc., plaintiff, for an Order of injunction *pendente lite* pursuant to Fed. R. Civ. Proc. 65; the Court having held a hearing on September 4, 1984 on plaintiff's motion for a preliminary injunction; the Court having considered the evidence and the argument of counsel and the papers submitted in connection therewith, and good cause having been shown.

IT IS ON THIS 25 day of September, 1984,

ORDERED that the motion of plaintiff, Merck & Co., Inc., for a preliminary injunction is hereby granted as follows:

1. Defendant, Par Pharmaceutical, Inc. and its officers, agents, servants, employees, affiliates and attorneys and all other persons in active concert or participation with them, or any of them, who receive actual notice of this Order by personal service or otherwise shall be and hereby are restrained and enjoined from directly or indirectly manufacturing, importing, selling, offering for sale, shipping, delivering, distributing or directing or causing or authorizing the manufacturing, importing, selling, offering for sale, shipping, delivering, or distribution of pharmaceutical products in or for use in the United States containing indomethacin in capsules bearing blue and white in combination as depicted in Exhibit A to the Affidavit of Douglas N. Durand sworn to June 14, 1984 and annexed hereto and/or representing or describing any indomethacin product of Par Pharmaceutical, Inc. which they or any of them manufacture, import, sell, offer for sale, ship, deliver or distribute as bearing the above described size, shape and color combination.

IT IS FURTHER ORDERED that all existing stocks of products containing indomethacin in blue and white capsules in the possession or under the control of Par Pharmaceutical, Inc., and its officers, servants, employees and affiliates who receive actual notice of this Order by personal service or otherwise shall be destroyed. This paragraph shall be stayed pending final disposition of any appeals; and

IT IS FURTHER ORDERED that delivery of a copy of this Order to the offices of defendant Par Pharmaceutical, Inc., 12 Industrial Drive, Saddle River, New Jersey or to defendant's counsel, Sheldon S. Lustigman, Esq., personally or to his offices at 158 Windham Road, Hillsdale, New Jersey 07642 by 5:00 p.m. on October 1, 1984 shall be deemed sufficient service of this Order upon said defendant.

IT IS FURTHER ORDERED that in accordance with the Final Judgment and Order of this date, this injunction is hereby made permanent.

ENTERED:

DICKINSON R. DEBEVOISE

U.S.D.J.

We hereby approve the form
of this Order.

SHANLEY & FISCHER, P.C.
Attorneys for Merck & Co., Inc.

By: _____
Ronald Gould

BASS & ULLMAN
Attorneys for Par Pharmaceutical, Inc.

By: _____
Lawrence H. Roth

_____
Sheldon S. Lustigman
Attorney for Par Pharmaceutical, Inc.

APPENDIX G

FINAL JUDGMENT AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, *MERCK & CO., INC. v. PAR PHARMACEUTICAL, INC.*, NO. 84-1559 (D.N.J. September 25, 1984)

United States District Court
for the
District of New Jersey

Honorable Dickinson R. Debevoise

Civil Action No. 84-1559

MERCK & CO., INC.,

Plaintiff,

vs.

PAR PHARMACEUTICAL, INC.,

Defendant.

FINAL JUDGMENT AND ORDER

The Court having held a hearing in this action on September 4, 1984 on Plaintiff's motion for a preliminary injunction; the Court having considered the evidence and argument of counsel; the Court having made certain findings of fact and conclusions of law in an opinion dated September 5, 1984 granting plaintiff's motion for a preliminary injunction; the Court, upon request of defendant having consolidated the hearing held on plaintiff's motion for a preliminary injunction with the final trial on the merits pursuant to Fed. R. Civ. Proc. 65(a)(2); defendant having requested the Court to enter its decision as a final judgment rather than a preliminary injunction; and plaintiff having consented to the entry of final judgment,

IT IS ON THIS 25 day of September, 1984,

ORDERED that the findings of fact and conclusions of law set forth in the Court's Opinion of September 5, 1984 granting plaintiff's motion for a preliminary injunction shall be and hereby are adopted as the Court's findings of fact and conclusions of law which constitute the grounds for entry of final judgment and it is

FURTHER ORDERED that to the extent necessary any conclusion of law will be deemed a finding of fact and any finding of fact will be deemed a conclusion of law; and it is

FURTHER ORDERED, ADJUDGED AND DECREED:

A. That upon consideration of all the evidence and for the reasons set forth above and in the Court's Opinion of September 5, 1984, plaintiff has established its claims under the New Jersey state law of passing off and unprivileged imitation and under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a);

B. That judgment is entered in favor of plaintiff and against defendant on the claims for relief set forth in the Complaint under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), New Jersey Statutes Annotated Section 56:4-1 and 56:8-2 and the common law of unfair competition of the State of New Jersey;

C. That the preliminary injunction issued on this day is made permanent;

D. Defendant's counterclaim and plaintiff's claim for an accounting shall be and hereby are dismissed with prejudice on the consent of the parties;

E. The parties by consent shall bear their own costs and attorneys fees to date.

DICKINSON R. DEBEVOISE

DICKINSON R. DEBEVOISE,
U.S.D.J.

We hereby approve the form of this Order.

SHANLEY & FISCHER, P.C.
Attorneys for Merck & Co., Inc.

By _____
Ronald Gould

BASS & ULLMAN
Attorneys for Par Pharmaceutical, Inc.

By _____
Lawrence H. Roth

_____
Sheldon S. Lustigman
Attorney for Par Pharmaceutical, Inc.

APPENDIX H

ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION OF THE UNITED STATES

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

ARTICLE VI, PARAGRAPH 2 OF THE CONSTITUTION OF THE UNITED STATES

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

§43(a) OF THE LANHAM ACT, 15 U.S.C. §1125(a)

§1125. False designations of origin and false descriptions forbidden

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation or origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any perosn who believes that he is or likely to be damaged by the use of any such false description or representation.

NEW JERSEY STATUTES ANNOTATED SECTION 56:4-1

56:4-1. Appropriation of name, brand, trade-mark, reputation or goodwill of maker by dealer in product of maker

No merchant, firm or corporation shall appropriate for his or their own use a name, brand, trade-mark, reputation or goodwill of any maker in whose product such merchant, firm or corporation deals.

NEW JERSEY STATUTES ANNOTATED SECTION 56:8-2

56:8-2 Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.

BEST AVAILABLE COPY

NO. 85-478

Supreme Court, U.S.
FILED
OCT 24 1985
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,
Petitioner,

vs.

MERCK & CO., INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

RONALD GOULD
Counsel of Record for Respondent,
Merck & Co., Inc.
131 Madison Avenue
Morristown, New Jersey 07960-1979
(201) 285-1000

SHANLEY & FISHER, P.C.
Attorneys for Respondent,
Merck & Co., Inc.
FRANK L. BATE
RENATE A. COOMBS
Of Counsel

Adams Press Corp., 1188 Raymond Boulevard, Newark, New Jersey 07102—(201) 623-8611

Counter-Statement of Question Presented

Should this Court exercise its certiorari jurisdiction to review evidence concerning the trade dress of a prescription drug to determine whether the District Court's fact findings regarding the torts of "unprivileged imitation" and "passing off" are clearly erroneous, where the findings are not in conflict with this Court's decision in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*")?

Statement Pursuant to Supreme Court Rule 28.1

Merck & Co., Inc., a publicly owned New Jersey corporation, has no parent companies. The following subsidiaries or affiliates are not wholly owned by Merck:

Arramara Teoranta

A.S.C. Service Co., Limited

Associated Pharmacuetical Products Limited

Astra/Merck, Inc.

Banyu Pharmacuetical Co., Ltd.

Charles E. Frosst (New Zealand) Limited

Floccotan (Proprietary) Limited

Kaneki & Co., Ltd.

Kelp Industries Pty. Limited

Kiinteisto Oy Irmelinpesa

Kronans Droghandel AB

Mannings Limited

Merck Sharp & Dohme (New Zealand) Limited

Merck Sharp & Dohme (Thailand) Ltd.

Merck Sharp & Dohme of Pakistan Limited

Merind Limited

Nippon Merck-Banyu Co., Limited

Seelman Pharmaceutical Co., Ltd.

Torii & Co., Ltd.

Torungavinnslan h.f.

TABLE OF CONTENTS

	PAGE
Counter-Statement of Question Presented	i
Statement Pursuant to Supreme Court Rule 28.1	ii
Table of Authorities	v
Opinions Below	1
Jurisdiction	2
Constitutional Provisions and Statutes	2
Summary of Argument	2
Counter-Statement of the Case	3
A. The preliminary injunction proceedings in the District Court	4
B. The District Court's entry of final judgment	12
C. The Third Circuit's affirmance and denial of rehearing *en banc*	12
Reasons for Denying the Writ	14
I. The sparing exercise of this Court's discretionary certiorari jurisdiction is not warranted to review the Court of Appeals' holding that the District Court's fact findings with respect to the tort of "unprivileged imitation" under federal and state law were not clearly erroneous	14

PAGE

II. In holding that Par is liable for the tort of "passing off" the District Court made no finding of fact which was clearly erroneous and applied the correct legal standard under state law 19

Conclusion 23

PAGE

Table of Authorities

Cases Cited

Beecham, Inc. v. *Camall Co.*, No. 81-1731 (D.N.J. June 14, 1984) 3

Beecham, Inc. v. *Zenith Laboratories, Inc.*, No. 81-1731 (D.N.J. Oct. 22, 1981) 3

Berenyi v. *Immigration Director*, 385 U.S. 630 (1967) 18

Ciba-Geigy Corp. v. *Bolar Pharmaceutical Co., Inc.*, 547 F. Supp. 1095 (D.N.J. 1982), *aff'd per curiam*, 719 F.2d 56 (3d Cir. 1983), *cert. denied*, 104 S.Ct. 1444 (1984) ("*Ciba-Geigy I*") 5, 8, 9, 19

Ciba-Geigy Corp. v. *Bolar Pharmaceutical Co., Inc.*, 747 F.2d 844 (3d Cir. 1984), *cert. denied*, 105 S.Ct. 2678 (1985) ("*Ciba-Geigy II*") 8, 9, 12, 13, 15, 16, 19

Compco Corp. v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964) 20, 21

Estate of Spiegel v. *Commissioner*, 335 U.S. 701 (1949) 20

Graver Manufacturing Co. v. *Linde Co.*, 336 U.S. 271 (1949) 18

Huddleston v. *Dwyer*, 322 U.S. 232 (1944) 20

Inwood Laboratories, Inc. v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*") ..... i, 10, 11, 13-22

Ives Laboratories, Inc. v. *Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom. Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982), *aff'd mem. on remand*, 697 F.2d 291 (2d Cir. 1982) 17

PAGE

Par Pharmaceutical, Inc. v. *Searle Pharmaceuticals, Inc.*, No. 85 C 2027 (N.D. Ill. Aug. 20, 1985) 3

SK&F, Co. v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), *aff'g* 481 F. Supp. 1184 (D.N.J. 1979) 5, 7-9, 11, 12, 15, 19, 21

Sears, Roebuck & Co. v. *Stiffel Co.*, 376 U.S. 225 (1964) 20, 21

United States v. *Johnston*, 268 U.S. 220 (1925) 3, 18

William R. Warner & Co. v. *Eli Lilly & Co.*, 265 U.S. 526 (1924) 15, 17

Statutes Cited

15 U.S.C. §1114, Lanham Act Section 32 ....11, 16, 17, 21, 22

15 U.S.C. §1125(a), Lanham Act Section 43(a) 2, 4, 5, 10, 11, 13, 16, 17, 20-22

Rules Cited

Fed. R. Civ. P. 52(a) 3, 21

Sup. Ct. R. 17 2

NO. 85-478

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

Opinions Below

The opinion of the United States Court of Appeals for the Third Circuit, dated May 29, 1985, affirming the judgment of the District Court, is not officially reported and is set forth at pages A-1 to A-5 of the appendix to the petition for certiorari filed by Par Pharmaceutical, Inc.

("Par"). The bench opinion of the District Court for the District of New Jersey, dated September 5, 1984, granting respondent's motion for a preliminary injunction, is not officially reported and is set forth at pages A-9 to A-22 of the appendix to the Par petition. The judgments of the Court of Appeals and the District Court are set forth at pages A-7 to A-8 and pages A-27 to A-29 of the Par appendix, respectively.

Jurisdiction

Merck & Co., Inc. ("Merck") refers the Court to the jurisdictional statement set forth at page 2 of the petition for certiorari filed by Par.

Constitutional Provisions and Statutes

Contrary to Par's assertion, Merck believes that no constitutional provisions and no New Jersey statutes are at issue in this case. The federal statutory provision involved herein is section 43(a) of the Lanham Act, 15 U.S.C. §1125 (a). This provision is set forth at page A-30 of the appendix to Par's petition.

Summary of Argument

Respondent Merck respectfully submits that the instant petition fails to present a single "special and important" reason warranting the issuance of a writ of certiorari. See Sup. Ct. Rule 17. On the contrary, the only issue raised by the disposition below is whether the Court of Appeals

correctly affirmed the District Court's findings of fact—which provided several alternative bases for its judgment under state and federal law—on the ground that those findings were not "clearly erroneous" under Rule 52(a) of the Federal Rules of Civil Procedure. Because that fact-bound determination presents no conflict with any decision of this Court or any other Circuit, and because this Court's extraordinary certiorari jurisdiction is not properly invoked "to review evidence and discuss specific facts," the petition should be denied. *United States* v. *Johnston*, 268 U.S. 220, 227 (1925).

Counter-Statement of the Case

Par's petition presents a misleading and distorted version of both the relevant facts and legal standards applicable to the issues raised by this case. Moreover, by mischaracterizing the courts within the Third Circuit as a haven for forum shoppers, petitioner attempts to create the impression of a conflict where none exists.[1]

---

[1] Seeking the perceived benefits of a forum outside the Third Circuit, Par commenced a declaratory judgment action in the Seventh Circuit. *See Par Pharmaceutical, Inc.* v. *Searle Pharmaceuticals, Inc.*, No. 85 C 2027 (N.D. Ill. Aug. 20, 1985). Rather than condone Par's imitation of a brand name manufacturer's trade dress, the District Court for the Northern District of Illinois entertained a motion for a preliminary injunction brought by the brand name manufacturer on its counterclaim and applied the same standard with the same result as that complained of here by Par. In addition, Par's assertion that the courts in the Third Circuit consistently side with brand name manufacturers is belied by two decisions relied upon by Par in proceedings before the District Court below. *See Beecham, Inc.* v. *Zenith Laboratories, Inc.*, No. 81-1731 (D.N.J. Oct. 22, 1981), and *Beecham, Inc.* v. *Camall Co.*, No. 81-1731 (D.N.J. June 14, 1984).

A. The preliminary injunction proceedings in the District Court.

Merck commenced this action on April 18, 1984, alleging that petitioner Par was engaged in unfair competition in violation of section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), as well as the New Jersey state laws against "unprivileged imitation" and "passing off." The complaint was filed when Merck learned that Par was soliciting purchases of indomethacin prescription drug products in sizes, colors and shapes duplicating the trade dress of Merck's INDOCIN brand indomethacin. At that time it was known that Par had not yet received clearance from the Food and Drug Administration ("FDA") to market indomethacin and it appeared that no such product was actually being shipped by Par.

During a June 8, 1984, deposition of a Par vice president, Merck learned that Par had a substantial inventory of look-alike product ready to be shipped as soon as the FDA granted clearance. Accordingly, Merck filed a motion for a preliminary injunction. On August 7, 1984, before the return date of Merck's motion, Merck learned during another deposition that Par had received FDA approval on August 6, had shipped INDOCIN indomethacin look-alike capsules on August 7, and had outstanding unfilled orders for many more millions of look-alike capsules. (A 10)[2]

On August 13, 1984, the District Court temporarily restrained Par from selling its generic version of Merck's product in confusingly similar trade dress and ordered Par to show cause why such conduct should not be pre-

---

[2] The designation A- — hereinafter refers to petitioner's appendix.

liminarily enjoined. After a brief period for additional discovery and the submission of affidavits and documentary evidence, counsel were heard on September 4, 1984.

On the following day, the District Court granted Merck's motion for a preliminary injunction. The reasons for the injunction's issuance were set forth in a bench opinion containing the District Court's findings of fact and conclusions of law. The District Court held that Merck was likely to succeed on the merits of its claims that Par's intentional copying of Merck's INDOCIN trade dress constituted independent violations of the New Jersey common law of "unprivileged imitation" and "passing off" and of the federal law of "unprivileged imitation" under section 43(a) of the Lanham Act, 15 U.S.C. §1125(a). The lower court reached these conclusions based upon its determination that the instant case was governed by the Third Circuit opinion in *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), *aff'g* 481 F. Supp. 1184 (D.N.J. 1979) (*"SK&F"*), and *Ciba-Geigy Corp.* v. *Bolar Pharmaceutical Co., Inc.*, 547 F. Supp. 1095 (D.N.J. 1982), *aff'd per curiam*, 719 F.2d 56 (3d Cir. 1983), *cert. denied*, 104 S. Ct. 1444 (1984) (*"Ciba-Geigy I"*). (A-14)

In addressing two elements of "unprivileged imitation," secondary meaning and nonfunctionality, the trial judge held with respect to the former that the evidence strongly supported Merck's position that the particular trade dress of its INDOCIN indomethacin had "acquired a secondary meaning denoting a common source of the product and denoting to doctors and pharmacists and at least to some patients that Merck was that source." (A-17) The District Court reached this conclusion in light of the following findings of fact: (1) Merck's continuous and exclu-

sive manufacturing of INDOCIN products since 1965, (2) Merck's continuous and exclusive marketing of INDOCIN products in the same trade dress for over nineteen years, (3) Merck's exclusive right to use INDOCIN as a trademark, (4) Merck's extensive advertising and promotion of INDOCIN brand indomethacin featuring the product's trade dress including direct promotion to patients themselves, (5) the steadily increasing and substantial sales of INDOCIN products, and (6) Par's intentional copying of the INDOCIN trade dress. (A-10 to A-13)

Merck had introduced evidence of sales aggregating more than one billion dollars and advertising expenses aggregating more than seventy-five million dollars. Merck also demonstrated that its promotional material featuring the INDOCIN indomethacin trade dress had been carried in journals read both by health care professionals and laymen and that its INDOCIN indomethacin trade dress had also appeared in books on prescription drugs directed to laymen. (A-12)

Finally, the record established that when Par commenced distribution of its indomethacin products, four other generic firms were already marketing indomethacin products in distinctly different trade dress. In fact, more than fifteen percent of all new prescriptions for indomethacin were being filled with these non-look-alike generic products. (A-12)

Stressing the extent of Par's admittedly intentional copying, the District Court found that

> [b]y design the Par product is almost indistinguishable from Merck's. Even the designation PAR which is superimposed upon the Par product appears to

> all but the most observant person to be the same symbol as Merck's MDS [sic] which appears on the INDOCIN capsule.[3] (A-17)

Significantly, the District Court found that a reason for Par's selection of a trade dress which slavishly copied the INDOCIN trade dress was "to obtain a competitive advantage over competing generic manufacturers of generic indomethacin who selected other colors." (A-13)

Turning to the second element of "unprivileged imitation," the District Court applied the *SK&F* criterion for determining nonfunctionality to the facts and found that none of the supposedly functional features of Merck's trade dress actually enhanced efficacy. (A-16; A-18 to A-19)

The evidence of nonfunctionality introduced by Merck pertained specifically to the INDOCIN indomethacin trade dress at issue in the litigation. Merck's evidence showed that there was no medical, pharmaceutical or manufacturing reason for its choice of a blue and white capsule trade dress. Merck demonstrated that neither the capsule nor

---

[3] On August 13, 1984, during oral argument regarding Merck's application for a temporary restraining order, the following exchange took place between Par's counsel and the District Court:

> Mr. Roth: They don't look like the Merck capsules.
>
> The Court: They sure look like that to me. I've seen them now for the first time.
>
> Mr. Roth: Blue and white, the same size.
>
> The Court: And the black thing. You have to squint to read it. If I just—bouncing these around in my hand, I can't for the life of me tell me which is which until I go down and read the writing on each one. If I were a purchaser, I would think those were the same pills from the same place.

the color combination was essential by evidence of the successful marketing abroad by its competitors of sixteen or more brands of indomethacin products in a variety of colors and in both tablet and capsule form. Nonfunctionality was also demonstrated by Merck's own use of an ivory or pale yellow capsule trade dress in foreign markets and by the commercial availability of capsules in hundreds, if not thousands, of color combinations.

Finally, contrary to Par's assertion, Dr. Hillel Ben-Asher, a physician testifying on behalf of Merck, did not support Par's claims of functionality. Dr. Ben-Asher testified that in his twenty-six years of medical practice it has been his experience that the appearance of prescription drugs bears no relationship to their therapeutic effect.

In stark contrast, Par introduced no evidence pertaining specifically to INDOCIN indomethacin trade dress. Par relied upon two theories—the first was that all brand name prescription drug trade dress becomes functional after a period of use. Par failed to demonstrate, in any way, that this theory actually applied to Merck's INDOCIN blue and white capsule trade dress.

Moreover, in rejecting this first theory, the lower court noted that arguments advanced by Par were the same as those urged unsuccessfully by the defendants in *SK&F* and *Ciba-Geigy I* and *II*. (A-18) The District Court then stated that

> [t]he evidence in this case and the findings in other cases establish that when a prescription drug used by patients over an extended period of time, is sold in the same . . . trade dress for many years, the trade dress does, to some extent at least, (1) make

> it easier for pharmacists and nurses to dispense drugs, (2) provide a way for patients to avoid commingling drugs, and (3) give the patient a feeling of continuity and security. (A-18) [Numbering added.]

However, the District Court concluded that these advantages which can be gained from copying the trade dress were "so minimal that they cannot serve to render the trade dress functional within the meaning of New Jersey law of unprivileged imitation."[4] (A-18 to A-19)

The court also stated that it was not persuaded by the evidence that use of look-alike generic drugs materially assists a doctor in dealing with an emergency overdose situation. (A-18)

The District Court noted that Par's second theory constituted the only argument which did not appear in *SK&F* and *Ciba-Geigy I* and *II*. Specifically, Par argued that the color blue comprising one element of Merck's blue and white capsule trade dress had independent therapeutic value because Merck selected it for the "soothing" response it would produce in patients. The trial court found this argument to be inherently unconvincing. The court reasoned that if Par had really believed that the color blue possessed therapeutic qualities, i.e. enhanced the drug's

---

[4] Commenting upon similar evidence of alleged functionality, the District Court in *Ciba-Geigy I* and *II* stated: "All of these contentions are predicated upon the claim that such trade dress is utilized for identification purposes. . . . Such appearance may be utilized as a secondary or incidental means of identification, but such use hardly rises to the level of functionality which would mandate or permit copying." 547 F. Supp. at 1111.

efficacy, Par would have simply selected an all-blue capsule for its indomethacin products instead of blue and white in the same pattern long used by Merck.[5] (A-18)

In finding that the INDOCIN trade dress was nonfunctional, the trial court stressed additional facts before it, including (1) the use of a wide range of different colors and shapes for the trade dress of antiarthritic drugs other than indomethacin, (2) the use of blue and white capsule trade dress for drugs in other therapeutic fields, and (3) the successful marketing of four other generic indomethacin products in the colors all green, pink and white, all orange and all white. (A-19) This last factor served as the basis for the trial judge's conclusion that "[a]ny functional uses of the blue and white color scheme were not sufficiently substantial to preclude [Merck's] competition from entering the market place." (A-19)

Having found Merck's INDOCIN trade dress nonfunctional under New Jersey common law, the trial Judge also rejected Par's argument that, with respect to section 43(a) of the Lanham Act, a different result was required by this Court's decision in *Ives*. Based on his analysis of the issues in *Ives* and of that case's procedural history, the

---

[5] Par alleges that Merck itself has recognized the therapeutic effect of color and claims that such recognition is evidenced by a Merck internal memorandum designating certain colors as the color of choice for a drug in a particular therapeutic area. (Petition at 6-7.) Whereas there is no evidence that the suggestions in this internal memorandum were ever followed, it is obvious that in the case of INDOCIN they were not followed because the memorandum post-dates the trade dress decision for INDOCIN by approximately twenty years. The study does not stand for the proposition that Par contends it does and the District Court did not agree with Par's reading.

trial judge concluded that *Ives* did not constitute a ruling on functionality under either section 32 or section 43(a) of the Lanham Act. (A-20)

As another basis for its ruling, the District Court also addressed Merck's "passing off" claim under New Jersey state law. The District Court found—as a matter of fact—a set of circumstances which warranted the conclusion that Merck was likely to succeed on the merits on its New Jersey common law "passing off" claim. (A-17)

This set of circumstances included (1) Par's admission of deliberately producing an exact copy of Merck's INDOCIN trade dress, (2) Par's use of this similarity as a selling point when promoting its product among pharmacists, (3) Par product being touted as an "INDOCIN GENERIC LOOK-ALIKE" by one of Pars customers, (4) Par's belief that there are pharmacists who are inclined to substitute generic products illegally, (5) the presence of a motive for illegal substitution, (6) the presence of an opportunity for illegal substitution, and (7) in light of the inclination, motive and opportunity for unauthorized substitution, Par's use of a warning label which the Court found to be wholly inadequate for the purported purpose of discouraging customers from unauthorized substitution. (A-17) On this basis, the District Court concluded that Par's conduct readily constituted the tort of "passing off" under New Jersey law as set forth in *SK&F*, 625 F.2d at 1062-63. (A-15 to A-16)

Finally, the District Court concluded that the remedies provided under the Lanham Act should be invoked as a means to further "the public . . . interest in drug manufacturers building and maintaining reputations for good quality products." (A-21)

On the foregoing basis, the District Court entered an order preliminarily enjoining Par from the sale and distribution of indomethacin in the INDOCIN trade dress. (A-22)

B. The District Court's entry of final judgment.

On September 25, 1984, at Par's urging and with Merck's consent, the District Court adopted its findings and conclusions on the motion for preliminary injunction as final and entered a permanent injunction and judgment against Par. (A-23 to A-25) Par then appealed to the Third Circuit.

C. The Third Circuit's affirmance and denial of rehearing *en banc*.

On May 29, 1985, the Third Circuit unanimously affirmed the District Court's permanent injunction. (A-5) In a memorandum opinion, the Court of Appeals agreed with the District Court's reliance on *SK&F* and stated:

> But what more strikingly compels us to uphold the district court's injunction is that after the district court in the case before us here had issued its opinion, our court decided another trade dress case, *Ciba-Geigy Corp.* v. *Bolar Pharmaceutical Co., Inc.*, 747 F.2d 844 (3d Cir. 1984) ("*Ciba-Geigy II*"). (A-4)

After reviewing the record, the briefs and arguments of counsel, the Court of Appeals held that the District Court had not only applied the correct legal standards, but had

also not committed any obvious errors in determining the facts. (A-4 to A-5)

With respect to Merck's claim for "unprivileged imitation" under New Jersey law, the Court of Appeals applied a three prong test: nonfunctionality, likelihood of confusion and secondary meaning. Recognizing that almost identical contentions of functionality had been unsuccessfully urged in *Ciba-Geigy II,* the Court of Appeals again found no error in the lower court's finding that, as a matter of fact, the blue and white trade dress was nonfunctional, that the imitation was likely to cause confusion and that Merck's blue and white capsules had acquired secondary meaning. (A-5)

As for Par's contention that the trial judge had erred in failing to read *Ives* as precluding him as a matter of law from evaluating the relevant evidence and concluding that the INDOCIN trade dress was nonfunctional, the Court of Appeals did not dignify with renewed discussion an issue it had laid to rest in *Ciba-Geigy II.* Detecting no error in the District Court's findings as to nonfunctionality and secondary meaning, the Third Circuit affirmed Merck's success on its federal cause of action under section 43(a) of the Lanham Act. (A-5)

With respect to Merck's New Jersey common law "passing off" claim, the Court of Appeals, following its decision in *Ciba-Geigy II,* affirmed the District Court's application of the "reasonable anticipation" standard under state law and found no clear error in the District Court's fact finding that Par could have reasonably anticipated that pharmacists would illegally substitute Par's drug for that of Merck. (A-4)

Following the panel's affirmance, Par petitioned the Third Circuit for rehearing or rehearing *en banc*. On June 25, 1985, that petition was denied, "no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc." (A-6)

Thereafter, Par filed the instant petition.

REASONS FOR DENYING THE WRIT

I. The sparing exercise of this Court's discretionary certiorari jurisdiction is not warranted to review the Court of Appeals' holding that the District Court's fact findings with respect to the tort of "unprivileged imitation" under federal and state law were not clearly erroneous.

Where the judgment affirmed by the Court of Appeals rested upon alternative findings of liability for "unprivileged imitation" under state and federal law as well as a finding of liability for "passing off" under state law and where none of these findings is in conflict with this Court's decision in *Ives,* the extraordinary certiorari jurisdiction of this Court should not be exercised.

Contrary to Par's contention (Petition at i and 10), the Third Circuit's affirmance of the District Court's non-functionality holdings under state and federal law does not "conflict" with this Court's limited disposition in *Ives.* There is no conflict in legal standards, as Par asserts. The difference in result between this case and *Ives* is attributable solely to the fact that two trial judges, after evaluating the evidence before them, reached different fac-

tual conclusions with respect to the particular issue before them. The Third Circuit's holding that the District Court's finding of nonfunctionality was not clearly erroneous is simply a fact-bound determination which is not worthy of certiorari.

Contrary to Par's contention, the District Court has not "announced a new rule that a trade feature is not functional, as a matter of law, if other companies were able to enter the market without imitating that feature, even if there are legitimate reasons to imitate." (Petition at 10.) Rather, the trial judge relied on the legal standard for functionality enunciated by the Third Circuit in *SK&F* (which in turn relied on this Court's decision in *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924) ("*Warner*")) and, applying that standard to the evidence before him, found that Merck's INDOCIN trade dress was nonfunctional. (A-18 to A-19)

Nor did the Third Circuit permit the application of a "new rule" when it affirmed the lower court's fact finding as not being clearly erroneous. In fact, the Court of Appeals felt "compelled" to uphold the District Court's injunction in this case by its own decision in *Ciba-Geigy II*. There the Third Circuit affirmed a fact finding of nonfunctionality by another trial judge who expressly applied the legal standard for functionality enunciated by this Court in *Ives*, finding no inconsistency between that standard and the one enunciated in *SK&F*.[6]

---

[6] In *Ives*, this Court noted that "[i]n general terms a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." 456 U.S. at 850 n. 10.

By mischaracterizing the holdings of the courts below and this Court's holding in *Ives,* Par attempts to create a conflict where none exists. As the Third Circuit noted in *Ciba-Geigy II,* any "assertion that *Ives* held that trade dress is functional as a matter of law is incorrect." 747 F.2d at 854 n. 7. The impact of this Court's holding in *Ives* was correctly analyzed by the District Court below.

Ives, the brand name manufacturer, instituted suit against Inwood, the manufacturer of the generic look-alike drug, under sections 32 and 43(a) of the Lanham Act. After a trial, the District Court found that Inwood's conduct did not violate section 32 since Inwood had not suggested, not even by implication, that pharmacists should dispense the generic drugs incorrectly as Ives' product. Ruling on Ives' section 43(a) claim, the District Court for the Eastern District of New York found on the basis of the evidence submitted in that case that the color scheme which Inwood copied was functional and did not indicate the drug's origin. (A-19)

The Court of Appeals for the Second Circuit concluded that Inwood had violated section 32 and reversed without reaching Ives' section 43(a) claim. Upon its review of the Second Circuit decision, this Court analyzed the law concerning contributory infringement in violation of section 32 and reversed the Court of Appeals because it erred in setting aside findings of fact without holding that they were clearly erroneous. (A-19)

Neither the Second Circuit nor this Court purported to rule on Ives' section 43(a) claim. (A-20)

Thus, the District Court in this action correctly held that *Ives* does not constitute a ruling on functionality of trade dress under either section 32 or section 43(a). (A-20) And certainly *Ives* does not create, as Par claims, a legal standard of functionality, but rather leaves untouched the traditional rule that functionality is a question of fact. *Warner,* 265 U.S. at 529.

A critical distinction between this case and *Ives* is that here the Third Circuit affirmed a district court finding of fact as not being clearly erroneous, whereas in *Ives* the Second Circuit reversed a district court finding of fact without holding that it was clearly erroneous.

It is not correct to say, as Par does, that in this case and in *Ives* "the lower courts have reviewed basically the same evidence of functionality." (Petition at 11) For example, evidence in the area of market entry differed dramatically. In *Ives,* there was evidence before the trial court that Inwood's parent company had discontinued the sale of a non-look-alike product because it had been difficult to sell. *Ives Laboratories, Inc.* v. *Darby Drug Co.,* 488 F. Supp. 394, 399 (E.D.N.Y. 1980), *rev'd,* 638 F. 2d 538 (2d Cir. 1981), *rev'd sub nom. Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.,* 456 U.S. 844 (1982), *aff'd mem. on remand,* 697 F. 2d 291 (2d Cir. 1982). Here, in contrast, the trial judge expressly noted that four other generic indomethacin products in distinctly different looking capsules were successfully competing with INDOCIN indomethacin (A-19). The District Court noted that Par could have done the same with its indomethacin product and "built

its own reputation as the other manufacturers of the generic product had done." [7] (A-20 to A-21)

In sum, the only issue properly raised by Par's petition with respect to "unprivileged imitation" under New Jersey law and the Lanham Act is whether the Third Circuit, applying the clearly erroneous standard, erred in affirming the District Court's fact finding of nonfunctionality. This issue hardly warrants the grant of certiorari. This Court had long held the view that "[w]e do not grant certiorari to review evidence and discuss specific facts." *United States* v. *Johnston,* 268 U.S. 220, 227 (1925). This Court has made it clear that "it 'cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.'" *Berenyi* v. *Immigration Director,* 385 U.S. 630, 635 (1967) (quoting *Graver Manufacturing Co.* v. *Linde Co.,* 336 U.S. 271, 275 (1949).[8] No such "obvious and exceptional" showing has been made here.

---

[7] Contrary to Par's assertion (Petition at 7), a Merck study referred to by Par did not address the issue of look-alike products versus non-look-alike products, but rather sought to compare substitution rates of products having distinct colors, shapes or markings (e.g. a green triangular tablet with a central hole) with the substitution rates of products having plain or nondistinctive appearances (e.g. a little white round pill). Moreover, the Merck report itself indicated that the difference between the substitution rate figures (7% versus 12%) was not statistically significant. The documents on their face belie Par's assertion and the trial judge, after full argument on those documents did not express any agreement with Par's reading.

[8] Indeed in *Ives* itself, Justice White stated that "if the issue presented in the petitions for certiorari had been whether the clearly-erroneous standard, although properly invoked, was erroneously applied, it is doubtful in my mind that this fact-bound issue would have warranted certiorari." 456 U.S. at 859.

II. In holding that Par is liable for the tort of "passing off" the District Court made no finding of fact which was clearly erroneous and applied the correct legal standard under state law.

The trial judge found as a matter of fact a set of circumstances which warranted the conclusion that Merck had succeeded on the merits on its "passing off" claim under New Jersey law. Evidence introduced by Merck and the findings of the District Court establish the existence of an inclination, motive and opportunity for unauthorized substitutions of Par's indomethacin product for Merck's INDOCIN indomethacin product. The evidence and findings also demonstrate that there was not only a reasonable anticipation, but also an actual expectation by Par that such unauthorized substitutions would occur. Specifically, against the background of a known inclination, motive and opportunity, Par affixed to its indomethacin products a label which was insufficient for the purported purpose of discouraging its customers from making unauthorized substitutions. In the absence of any real deterrant effect, the natural effect of Par's warning label was to highlight the possibility of substitutions and, therefore, augment a known propensity.

Par does not contend that the District Court's findings of fact were clearly erroneous or did not meet the standards for a finding of "passing off" under state law articulated in *SK&F* and *Ciba-Geigy I* and *II*. Rather, Par argues that the Third Circuit's affirmance of the District Court's reliance on these standards was in error because, Par asserts, *Ives* rejected the *SK&F* "reasonable anticipation" standard for the tort of "passing off."

Par's petition advances, as a reason why this Court should grant certiorari, an issue which neither the District Court nor the Third Circuit addressed—whether *Ives* overruled the "reasonable anticipation" test for the tort of "passing off" under section 43(a) of the Lanham Act. (Petition at 13-17.) Even though briefed by both parties before both courts below, neither court found it necessary to reach this issue where the judgment affirmed by the Court of Appeals rested upon three alternative theories of liability—"unprivileged imitation" under federal and state law and "passing off" under New Jersey common law. The applicability of the "reasonable anticipation" test was discussed only in connection with New Jersey law. To grant certiorari to resolve an issue not reached below would clearly violate this Court's own rule against rendering advisory opinions. Indeed, there is no need to reach this issue, since the alternative holdings with respect to "unprivileged imitation" under federal and state law provide an independently sufficient basis to support the judgments below.

Nor is the lower courts' interpretation of New Jersey law a matter worthy of certiorari. Ordinarily this Court accepts and therefore does "not review, save in exceptional cases, the considered determination of questions of state law by the intermediate federal appellate courts." *Huddleston* v. *Dwyer,* 322 U.S. 232, 237 (1944); *Estate of Spiegel* v. *Commissioner,* 335 U.S. 701, 707-708 (1949).

Par's contention that the Third Circuit's interpretation of New Jersey law contravenes this Court's holdings in *Sears, Roebuck & Co.* v. *Stiffel Co.,* 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting, Inc.,* 376 U.S. 234 (1964), is also without merit. In *Sears* and *Compco,*

this Court held that a state may not impose liability upon a competitor for copying an unpatented product and thereby grant a perpetual state-protected design patent. *Sears,* 376 U.S. at 231-32; *Compco,* 376 U.S. at 237-38. But this Court left undisturbed state laws of unfair competition. Plainly contemplating that there would be some means, such as trade dress or labeling, by which a manufacturer could identify his product and distinguish it from similar products, this Court wrote in *Sears*:

> Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods.

376 U.S. at 232 (footnote omitted; quoted in *SK&F,* 625 F.2d at 1064).

Even if the District Court had found a "passing off" violation of section 43(a) on the basis of the "reasonable anticipation" standard, which it did not do, there would still be no conflict with *Ives* because that case, unlike this one, did not involve a claim of "passing off" under section 43(a). In *Ives,* this Court never reached the section 43(a) claim. The reversal of the Second Circuit for failure to comply with Rule 52's clearly erroneous standard was limited to plaintiff's claim of contributory trademark infringement under section 32 of the Lanham Act. This Court's opinion, written by Justice O'Connor, concluded with the statement:

> Although the District Court also dismissed Ives' claims alleging that the petitioners violated Section 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because Section 43(a) prohibits a broader range of practices than does Section 32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

456 U.S. at 858-59 (quoted by the trial court below at A-20).

No matter how strenuously Par attempts to create the impression of a conflict between this Court's decision in *Ives* and the lower courts' holding in this case, no such conflict does in fact exist.

CONCLUSION

It is submitted that the Court should deny issuance of its writ to review the decision of the Court of Appeals because petitioner has failed to identify any of the special and important reasons necessary for acceptance of jurisdiction. The decision below does not conflict with any of this Court's holdings. Par's petition should therefore be denied.

Respectfully submitted,

RONALD GOULD
Counsel of Record for Respondent,
Merck & Co., Inc.

SHANLEY & FISHER, P.C.
Attorneys for Respondent,
Merck & Co., Inc.
FRANK L. BATE
RENATE A. COOMBS
Of Counsel

Dated: October 22, 1985

Supreme Court, U.S.
FILED
OCT 31 1985
JOSEPH F. SPANIOL,
CLERK

No. 85-[illegible]8

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

BEST AVAILABLE COPY

TABLE OF CONTENTS

	Page
Table of Contents	i
Table of Authorities	ii
Argument	1
Conclusion	6

TABLE OF AUTHORITIES

Cases Cited:	Page
Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964)	3-4
Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844 (1982)	*passim*
Sears, Roebuck & Co. v. Stiffel, 376 U.S. 225 (1964)	3-4
Statutes Cited:	
15 U.S.C. §1125(a)	4

No. 85-478

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

ARGUMENT

Merck & Co., Inc. ("Merck") states in opposition to the Petition that the issues below are too "fact-bound" to warrant review and that the decision below is not contrary to *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). This statement is entirely incorrect. In fact, Par Pharmaceutical, Inc. ("Par") was found liable under a rule of law contrary to *Inwood*.

In this case, the district court made findings of fact that Par had three legitimate reasons to use blue and white capsules for its version of indomethacin. The court found that these advantages of imitation provided benefits to patients and health care professionals. Par does not quarrel with these findings; nor apparently does Merck. There is thus no "fact-bound" dispute in which the Petition seeks to embroil the Court.

The issue in this case is a legal one. The holding of the lower courts resulted from the application of an incorrect legal standard of what constitutes functionality. The rule of law in the lower court was that a trade dress feature is not functional as a matter of law if a competitor can enter the market without imitation. Merck seeks to obfuscate this issue by claiming that the findings below were subject to a "clearly erroneous" standard of review. The ultimate ruling of nonfunctionality, however, involves a mixed question of law and fact. In reviewing the Second Circuit decision on functionality in *Inwood*, this Court itself drew the distinction, stating:

> "If the District Court erred as a matter of law, the Court of Appeals should have identified the District Court's legal error. If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous." *Inwood v. Ives*, 456 U.S. at 857 n.20.

Whether patients obtain benefits unrelated to source identification by virtue of trade dress imitation is indeed a question of fact subject to the "clearly erroneous" standard. Whether such benefits establish functionality, however, is a question of law.

Merck also asserts that the new standard of law below governing functionality does not conflict with *Inwood*. This is grossly inaccurate. In *Inwood*, the brand-name company tried to make an important issue of the fact that competitors could and had for some time sold generic substitutes without imitating the trade dress. Brief for the Respondent at pp. 11-12; 21; 45. The issue was even addressed at some length at oral argument.

Despite the existence of these non-imitative generics, the Court upheld the *Inwood* district court ruling of functionality based upon the same findings of legitimate advantages as those found by the district court here. The *Inwood* holding and the rule of law applied by the courts below cannot both be correct.

Merck's argument that there is no conflict between this case and *Inwood* is without merit. In opposing the Petition, Merck asserts that the only difference between this case and *Inwood* is that the two district courts simply made different findings. This is untrue. The two district courts made the same findings of fact as to the legitimate reasons for and advantages of imitation. The real difference between this case and *Inwood* is that the district courts applied two entirely different rules of law as to what constitutes functionality for prescription drug trade dress.

Merck further contends that Par is urging a rule that would preclude a district court from considering evidence of nonfunctionality. This is also incorrect, for Par would have welcomed an opportunity below to address evidence that special circumstances applied to INDOCIN. If, for example, Merck showed that no other drug should be taken concurrently with indomethacin, and that therefore patients would not commingle indomethacin, it could vitiate that element of trade dress functionality. The undisputed record here, though, is just the opposite. Merck introduced no evidence that special circumstances applied, and indeed INDOCIN is precisely a product for which continuity of color should be maintained.[1]

---

[1] In Point II of the Petition, Par also showed that the Third Circuit improperly applied the " 'watered-down' and incorrect" standard of reasonble anticipation. In response, Merck asserts a meaningless semantic point, claiming that there was not only reasonable anticipation of passing off, but "actual expectation" of it. When *Inwood* requires an act of intentional inducement, the new term "expectation" cannot rationally support liability anymore than "anticipation" did. Merck further argues that *Sears-Compco* "left undisturbed state laws

(footnote continued)

Finally, Par wishes to make clear that the dispute over the legal standard of functionality raised in this case involves significant social consequences for the industry and the public, particularly the elderly and the poor. The injunction which Merck succeeded in obtaining below has a very real and undesirable effect on the market for prescription drugs.

By virtue of the decisions below, patients who want to use the blue and white color of indomethacin as a means of assuring themselves that they are getting the right medication, irrespective of source, can purchase only Merck's product. Patients who commingle a number of drugs and who rely upon the appearances of those drugs to know which to take at a particular time can purchase only Merck's product if they want to avoid mistakes and confusion. Hospitals and nursing homes that want to avoid dispensing errors and patient confusion and anxiety when a generic substitute is dispensed in an unfamiliar color can purchase only Merck's product.

When Par is enjoined from meeting the legitimate demand for these non-source benefits of color continuity, it is placed at an unfair competitive disadvantage. Patients are forced to pay higher prices for a product which is subject to an improper court-ordered monopoly.

Par respectfully believes that such a result is entirely beyond the proper scope of protection afforded by Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), and an indirect obstruction to state and federal laws encouraging generic substitution.

Having succeeded below, Merck naturally argues that these issues are fact-bound and undeserving of Supreme Court review. The real view of the brand-name industry, however, was presented

---

of unfair competition." Merck Brief at p. 21. This is not correct. In those very cases, the Court limited the scope of state laws of unfair competition. As Par has demonstrated in its Petition, what *Sears-Compco* prohibits state law from doing — imposing liability where there is imitation, but no act of deception — is exactly what was done below.

to this Court in *Inwood*. At that time, the Pharmaceutical Manufacturers Association, of which Merck was, and is, a leading member, said to this Court:

> "We submit, however, that this [functionality] is not an issue of fact, to be decided anew—and perhaps inconsistently—in each case. The same issue arises in every 'look-alike' case, and the arguments presented do not vary according to the particular drug at issue. It would be irrational to hold that the result in each case depends upon how a particular fact-finder happens to evaluate the particular record made on these matters of general applicability. There must ultimately be one rule as to whether 'look-alike' generic drugs serve any legitimate purpose." Brief of the Pharmaceutical Manufacturers Association as Amicus Curiae at pp. 14-15 [footnotes omitted].

Par shares this view of the PMA. Resolution of the color issue would be in the interest of the pharmaceutical industry, the government and the consuming public. Merck's position would lead only to continued litigation and uncertainty. Par respectfully urges the Court to review the judgment of the Third Circuit. In light of the conflict between the lower courts and the *Inwood* decision, Par believes that if this issue is to be finally settled, it is of such public importance as to warrant a review on the merits.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Petition of Par, we respectfully request that a Writ of Certiorari be issued to review the judgment below.

Respectfully submitted,

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

Of Counsel
LAWRENCE H. ROTH

(2)

No. 85-478

OCT 18 1985

JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN SUPPORT OF PETITION FOR CERTIORARI

MILTON A. BASS
General Counsel
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017
(212) 838-3720

BEST AVAILABLE COPY

17pp

TABLE OF CONTENTS

	Page
INTEREST OF THE *AMICUS CURIAE*	1
ARGUMENT	2
USE BY GENERIC DRUG MANUFACTURERS OF THE SAME SIZE, SHAPE AND COLOR AS BRAND-NAME DRUGS LEGITIMATELY ASSISTS THE SAFE USE AND ACCEPTANCE OF GENERIC DRUGS AND PROVIDES LEGITIMATE BENEFITS TO PATIENTS AND HEALTH CARE PROFESSIONALS ...	2
A. The Unique Structure of the Pharmaceutical Industry	3
B. The Brand-Name Companies Are Not In Favor of Generic Competition	5
C. Color is Widely Used and Accepted as an Important Functional Element of Prescription Drug Appearance	6
CONCLUSION	11

TABLE OF CITATIONS

Cases Cited: **Page**

Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844 (1982) 9

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) 7

Statutes Cited:

Drug Price Competition and Patent Restoration Act of 1984, P.L. No. 98-417, 98 Stat. 1585, Sept. 24, 1984 4

21 C.F.R. §314.2 4

Other Authorities Cited:

Biron & Caringhan, *Chromo Confusion: A New Type of Pill-Pill 'Interaction' in Cardiology*, 110 CMA JOURNAL 1346-48 (June 22, 1974) 6

Blumenthal, Burke & Shapiro, *The Validity of Identical Matching Placebos*, 31 ARCH. GEN. PSYCH. 214 (Aug. 1974) 6

Capsugel . . . Introduces a New Color Series for Appearance and Effect . . . Luscher Palette (Parke-Davis, Divison of Warner-Lambert Co. 1982) 7-9

Capsule Color Considerations (Parke-Davis, Division of Warner-Lambert Co. 1980) 7

Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981) 3

	Page
Competitive Problems in the Drug Industry: Hearings before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business (93rd Cong., 2d Sess. 1974)	3
Dichter, *Handbook of Consumer Motivations*, 228 (1964)	7
Drug Product Selection, Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979)	3
47 F.R. 444, 447 col. 2 (Jan. 5, 1982)	7
F-D-C Reports, T&G-2 Sept. 9, 1985	10
Gowdy, et al., *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96 CAN.MED. ASS'N J. 1317, 1320 (1967)	6
Improving Medication Compliance, Summaries of Symposium Presentation (November 1984)	9-10
Jacobs & Nordan, *Classification of Placebo Drugs: Effect of Color*, 49 PERCEPTUAL & MOTOR SKILLS 367-372 (1979)	6
Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954)	7
Note, *Consumer Protection and Prescription Drugs: The Generic Drug Laws*, 67 KY.L.J. 384 (1978-79)	4
Plevan & Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. L.J. August 12, 1985	10

Page

Prescription Drug Labeling and Price Advertising, Hearings Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce (94th Cong., 2nd Sess. April 22, 1976) 10

Rados, *FDA Consumer* (October 1985) 3, 5

Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978) 3

Schapira, *et al.*, *Study on the Effects of Tablet Colour in the Treatment of Anxiety States* 2 BRIT. MED.J. 446-449 (1970) 6

Schwartz, *The Elderly Patient and His Medications*, GERIATRICS, 517 (June 1965) .. 7

Trouton, *Placebos and Their Psychological Effect*, 103 J.MENTAL SCI. 344 (1957) 7

Washington Drug Letter, Vol. 17, No. 38 (Sept. 23, 1985) 5-6

No. 85-478

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN SUPPORT OF PETITION FOR CERTIORARI

INTEREST OF THE AMICUS CURIAE

The National Association of Pharmaceutical Manufacturers ("NAPM") respectfully submits this *amicus curiae* brief in support of the petitioner Par Pharmaceutical, Inc. ("Par"). NAPM requests that the Court grant the petition for certiorari to resolve the still ongoing dispute between brand-name and generic drug manufacturers over product appearance.

NAPM is a national trade association representing more than 100 manufacturers and distributors of multi-source prescription and over-the-counter drug products, veterinary drugs, and vitamins and other dietary supplements. Since 1955, NAPM has been the leading voice for what is commonly known as the generic drug industry. In this capacity, NAPM has appeared in the courts as an *amicus* and as a party, including participation as *amicus* in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). NAPM has also appeared before administrative tribunals, has regularly participated in U.S. Food and Drug Administration ("FDA") rulemaking procedures, and frequently appeared in hearings before Congress and state legislatures. NAPM has sponsored educational seminars, bringing together representatives of the pharmaceutical industry with the scientific and legal community, as well as officials of FDA and the Drug Enforcement Administration. NAPM has also been responsible for development of the solid dosage form identification system for over 600 drugs. Petitioner Par, one of the leading generic drug manufacturers, is a member of NAPM.[1]

ARGUMENT

USE BY GENERIC DRUG MANUFACTURERS OF THE SAME SIZE, SHAPE AND COLOR AS BRAND-NAME DRUGS LEGITIMATELY ASSISTS THE SAFE USE AND ACCEPTANCE OF GENERIC DRUGS AND PROVIDES LEGITIMATE BENEFITS TO PATIENTS AND HEALTH CARE PROFESSIONALS

This case involves the role of generic prescription drugs in the national system of health care. Brand-name companies would prefer that smaller generic competitors not exist; short

[1] The General Counsel of the NAPM is a member of the firm which represents petitioner Par.

of that, efforts of the large brand-name companies have been directed to impeding the acceptability of generic drugs in the marketplace. The "size, shape and color" issue is the product of such an effort.

A. The Unique Structure of the Pharmaceutical Industry

At the root of the dispute raised by Par's petition for certiorari are certain commercial realities. The most significant of the realities is that Par and other generic manufacturers sell their products for far less than do brand-name companies. Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978); Rados, *FDA Consumer* (October 1985). This dual pricing structure operates at both the wholesale and retail level — pharmacists pay less for generic drugs, and patients in turn realize substantial savings when the pharmacist dispenses a generic drug. In addition, the success of generic drug competition serves as a market force reducing the price of brand-name drugs themselves. Thus, obstacles to generic competition not only enhance the volume of brand-name business, but also increase the per unit profitability of brand-name companies. *Competitive Problems in the Drug Industry*: Hearings before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, at 10, 268 (93rd Cong., 2d Sess. 1974); *Drug Product Selecton*, Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979); *Competition in the Drug Industry*: Hearing Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981).

The role of generic drugs is therefore of tremendous importance. Approximately 20 billion dollars per year are involved. The elderly and the poor are hit particularly hard by the high prices charged by brand-name companies. In addition, such price differentials are implicated in government purchase cost-containment programs. The burden of paying for brand-name drugs in such circumstances falls on taxpayers generally. In short, the lower prices for generic drugs can result in savings

of millions of dollars in the containment of health care costs of consumers, the federal government, Medicare and Medicaid programs, the armed services, including the Veterans Administration, state and local governments, and private hospitals.

Another major reality in the prescription pharmaceutical industry is that the ultimate user of the product plays almost no role in selecting the product. Because state and federal laws prohibit consumer use without a prescription, it is the physician who chooses the drug product. In this unique market, Merck and other brand-name companies engage in extensive advertising directed to physicians, not consumers.

The final significant reality in this industry is the nature of government regulation. Before the mid-1970's, a prescription written in the brand-name of the product could be filled only with that brand. In 1972, 47 states had such antisubstitution laws.

Recognizing that promotional efforts during patent life tended to obscure the generic names of pharmaceuticals, and the habit of physicians to identify a product by its brand name, the states began enacting substitution statutes. These statutes encourage generic substitution by setting forth those circumstances where a generic product may, or must, be dispensed, even if the physician has written the prescription by using the brand name. *See, e.g.*, Note, *Consumer Protection and Prescription Drugs: The Generic Drug Laws*, 67 KY.L.J. 384 (1978-79).

By way of recent statutory amendments, generic drug manufacturers may now generally obtain FDA approval under an abbreviated process. 21 C.F.R. §314.2 (superceded); Drug Price Competition and Patent Restoration Act of 1984, P.L. No. 98-417, 98 Stat. 1585, Sept. 24, 1984. FDA must still approve these products as safe and effective based upon scientific substantiation, but without the submission of reports of unnecessary and duplicative testing.

These changes in government regulation evidence a philosophy by Congress, FDA and all 50 states encouraging generic substitution. FDA has recently noted:

> "[T]he potential for reducing U.S. health-care costs through wider availability of generic drugs prompted Congress to pass the law last year that streamlined FDA's approval process for generics. When President Reagan signed the law, he noted that 'the American people will save money, and yet receive the best medicine that pharmaceutical science can provide.' " Rados, *FDA Consumer* (October 1985).

Merck and the brand-name industry want to derail this philosophy by misusing the trademark laws to impose a stigma upon generic drugs.

B. The Brand-Name Companies Are Not In Favor of Generic Competition

The brand name companies have generally contended that they do not oppose generic competition, only unfair generic competition. Economic reality and the pattern of behavior by the brand-name industry belie this contention.

In the 1970's, the brand-name pharmaceutical industry led the fight against passage of substitution laws. Now that these laws have been passed in all 50 states, and in the District of Columbia and Commonwealth of Puerto Rico, it is axiomatic that these laws have served as a stimulus to substantial savings to consumers.

The focus of brand-name efforts against generic competition have now shifted from the legislative arena to the marketplace. A principal method is product disparagement. Sandoz, for example, has marketed a product called Mellaril[R] for many years. Faced with generic competition, Sandoz placed numerous advertisements disparaging the quality of generic substitutes. In response, FDA has recently directed Sandoz to discontinue such activities and informed Sandoz that:

> "[Y]our continued use of misleading promotional materials and your activities aimed at discrediting

competing thioridazine products without scientific basis are flagrant, repeated and willful violations of the FD&C Act." *Washington Drug Letter*, Vol. 17, No. 38 (Sept. 23, 1985).[2]

The "size, shape and color" issue is another example of efforts to thwart generic competition. In this case, for example, Merck conducted a study of the effect of appearance on substitution rates. Merck's goal was to create "a strategy to reduce the impact of generic competition . . ." The study recommended the use of different appearances between brand-name and generic drugs, not to prevent illegal substitution, but "on the theory that patients would be upset if an unfamiliar pill was substituted for a familiar one."

C. Color is Widely Used and Accepted as an Important Functional Element of Prescription Drug Appearance

Par has presented evidence in this case consisting of expert witnesses and Merck documents which show the functionality of capsule colors. The fact of the functionality of capsule colors is widely known in the pharmaceutical industry. It has been shown that the "placebo" effect which is inherent in any drug, and indeed some aspects of a drug's efficacy, are related to the color configuration of a given product. *See generally*, Schapira, *et al., Study on the Effects of Tablet Colour in the Treatment of Anxiety States* 2 BRIT. MED.J. 446-449 (1970); Jacobs & Nordan, *Classification of Placebo Drugs: Effect of Color*, 49 PERCEPTUAL & MOTOR SKILLS 367-372 (1979); Blumenthal, Burke & Shapiro, *The Validity of Identical Matching Placebos*, 31 ARCH.GEN.PSYCH 214 (Aug. 1974); Biron & Caringhan, *Chromo Confusion: A New Type of Pill-Pill 'Interaction' in Cardiology*, 110 CMA JOURNAL: 1346-48 (June 22, 1974); Gowdy, et al., *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96

[2] Searle has also recently engaged in a pattern of advertising intended to disparage the quality of FDA-approved generic substitutes for Norpace®.

CAN.MED. ASS'N J. 1317, 1320 (1967); Schwartz, *The Elderly Patient and His Medications*; GERIATRICS, 517 (June 1965); Dichter, *Handbook of Consumer Motivations*, 228 (1964); Trouton, *Placebos and Their Psychological Effect*, 103 J.MENTAL SCI. 344 (1957); Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954). *Cf.*, 47 F.R. 444, 447 col. 2 (Jan. 5, 1982) (FDA panel notes that major drawback in use of activated charcoal as antitoxin is its black color, which often causes children to refuse it). *See also Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569, 572 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960).

Indeed, brand-name drug companies themselves recognize this aspect of color functionality. The leading manufacturer of pharmaceutical capsules is Parke-Davis, which has extensively promoted the functionality of capsule colors in two publications entitled: *Capsule Color Considerations* (Parke-Davis, Division of Warner-Lambert Co. 1980) ("Parke-Davis 1980") and *Capsugel . . . Introduces a New Color Series for Appearance and Effect . . . Luscher Palette* (Parke-Davis, Division of Warner-Lambert Co., 1982) ("Parke-Davis 1982"). In Parke-Davis 1980, it states:

> *"Parke-Davis Can Provide you with the 'Color Edge'*
>
> Our color laboratory, our equipment and our color experts are at your command to come up with the right colors for you. Contact our technical sales representative. Show him the color combination you have in mind .... If you need guidance in psychologically appropriate colors, we can provide several papers on the subject. Better still, let our color consultants come up with a few suggestions."

In another promotional piece, Parke-Davis sets forth the color strategies to be utilized by drug manufacturers. As described by Professor Max Luscher, the world's foremost authority on the psychology of color:

"The Choice of Appropriate Capsule Colors

In traffic signs, color is recognized by everybody as a signal, as it is in clothing as well as in packages such as capsules. Every signal exerts an effect. Most of them – as for instance the red stop light and dress colors – exert their effect without the observer realizing he has consciously taken note. The action of a pharmaceutical preparation should be recognizable from the color in exactly the same way. It is the function of the color of a capsule to transmit the correct signal.

* * *

Two-color capsules, on the other hand, where the two parts have different colors, indicate a change from one condition to another, namely from a state of illness to one of effective therapy. If one part of the capsule is red, irritation and inflammation are indicated, whereas a dark blue color of the other part represents the sedation which the preparation is aimed to achieve.

Since one color alone indicates only a general property, whereas two are a sign of a special one, most firms – and products – characterize their image with at least two colors. The same applies to preparations put up in capsules. With two colors, identification becomes much more accurate.

* * *

It is obvious, however, that a preparation will be taken more regularly if it is packaged in a color the patient finds pleasant and suggestive of a favorable effect.

* * *

> . . . [t]he following examples of functional color combinations will furnish an idea of which color effect is appropriate for a desired therapeutic effect.
>
> The colors chosen are most effective when they clearly express the action of the preparation; this functional aspect has priority . . ."

Parke-Davis 1982 at 3.

The precedent of this Court, *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), the evidence in this case, and common sense establish both the existence and the importance of the functional role of color. If, for example, one opened up a new bottle thought to contain aspirin, but found green tablets, one would think that the product was not aspirin. It is not at all a question of source, but of product identification. In this case, all the experts likewise testified that patients frequently think a mistake had been made when they received unfamiliar pills, but usually appeared to accept the explanation that a generic was dispensed. If such patient confusion was produced because they thought they were getting a different brand of the same medicine, they would hardly be relieved to learn that they were getting a generic substitute.

NAPM takes strong issue with the viewpoint that the advantages fostered by the use of the same size, shape and color for prescription drugs are "minimal" for any reason.

Some generic manufacturers now choose not to imitate product appearance. When they decline to imitate, patients and health care professionals are deprived of the tools that assist in proper compliance and product identification. NAPM believes that patient compliance is a vitally important issue facing health care today. Indeed, the President of the National Pharmaceutical Council, an arm of the brand-name drug industry, has himself characterized noncompliance as a "major public

health problem." *Improving Medication Compliance*, Summaries of Symposium Presentation (November 1984). Continuity of color in the dispensing of prescription drugs can only be an instrument of assistance to physicians, nurses, pharmacists, and patients in solving this problem:

> "Also, as there is always a certain amount of apprehension about taking medications, even those prescribed by a trusted physician, imagine the problems that would be created when the blood pressure pills are one month pink and the next month white and when those that were round one month are the next month rectangular, square or octagonal. The anxiety produced by repeated exposure to unfamiliar size, shape, and color would be sufficient to cause some people to discontinue their treatment program either in whole or in part. I need not detail the damage and even deaths that would result as a consequence of this particular problem." Testimony of Lawrence A. Tillis, M.D., *Prescription Drug Labeling and Price Advertising*, Hearings Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce at 176 (94th Cong., 2nd Sess. April 22, 1976).

NAPM believes it is unwise to penalize Par and the users of its product by denigrating the legitimate advantages of imitation as minimal. The brand-name industry's attempt to stigmatize generic drug products by imposing color changes will finally succeed absent intervention by this Court. Indeed, industry and legal commentators have pointed to the need for resolution by this Court as the controversy continues to grow. Plevan & Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. L.J. August 12, 1985; *F-D-C Reports*, T&G-2 Sept. 9, 1985.

If the brand-name companies continue to be successful in using the Lanham Act to extend their patent monopolies to the appearances to which the public is accustomed, patients and

health care professionals will be deprived of the undisputed legitimate advantages of trade dress imitation. NAPM respectfully believes that this threat to effective competition in the pharmaceutical industry is of vital importance to its members and to the public, and that certiorari is needed to resolve these issues.

CONCLUSION

It is respectfully submitted that a writ of certiorari be issued to the United States Court of Appeals for the Third Circuit as requested by Par Pharmaceutical, Inc.

Respectfully submitted,

MILTON A. BASS
General Counsel
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017
(212) 838-3720

Of Counsel:
LAWRENCE H. ROTH